UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF TENNESSEE
KNOXVILLE DIVISION

In re Provectus Biopharmaceuticals, Inc. Securities Litigation	Case No. 3:14-cv-00338-PLR-HBG CLASS ACTION District Judge Pamela L. Reeves Magistrate Judge H. Bruce Guyton DEMAND FOR JURY TRIAL

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAW

TABLE OF CONTENTS

Lead Plaintiff Fawwaz Hamati ("Plaintiff" or "Hamati"), individually and on behalf of all others similarly situated, by and through Plaintiff's undersigned attorneys, for Plaintiff's complaint against defendants, alleges the following based upon personal knowledge as to Plaintiff and Plaintiff's own acts, and upon information and belief as to all other matters based on the investigation conducted by and through Plaintiff's attorneys. The investigation included, *inter alia*, a review of Securities and Exchange Commission ("SEC") filings by Provectus Biopharmaceuticals, Inc. ("Provectus" or the "Company"), securities analysts' reports and advisories about the Company, press releases, conference calls, and other public statements issued by the Company and/or individual defendants, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

I. NATURE OF THE ACTION

1. This is a federal securities class action on behalf of all persons who purchased or otherwise acquired Provectus publicly-traded stock between December 17, 2013, and May 22, 2014, inclusive (the "Class Period"), against Provectus and certain of its officers and/or directors for violations of the Securities Exchange Act of 1934 (the "Securities Exchange Act") and Rule 10b-5 promulgated thereunder.

2. Defendant Provectus, formerly Provectus Pharmaceuticals, Inc., is a development-stage pharmaceutical company that is engaged in developing treatments for oncology and dermatology indications.

3. During the Class Period, Provectus was focused on developing two prescription drug candidates. The Company's 2013 Form 10-K, filed March 13, 2014 (the "2013 10-K"), described the Company's "primary business" as "developing our oncology and dermatology

prescription drug candidates, PV-10 and PH-10." Along with PH-10 (intended for the treatment of psoriasis and atopic dermatitis), PV-10, the drug candidate at issue herein, was one of only two drugs that made up the Company's "primary business."

4. Throughout the Class Period, Defendants violated the federal securities laws by disseminating materially false and misleading statements to the investing public regarding the commercialization of PV-10. As a result of Defendants' misstatements and omissions, as alleged herein, Provectus stock traded at artificially inflated prices during the Class Period, reaching a high of $6.03 per share on January 23, 2014. However, after the revelations set forth herein were absorbed by the market, the Company's stock was hammered by massive sales, sending the stock's price plummeting to an ultimate decline of more than 65% of its Class Period high.

II. OVERVIEW OF THE ACTION

5. In the years leading up to the Class Period, Provectus was focused upon obtaining FDA approval of PV-10 for the treatment of metastatic melanoma. An April 29, 2010, press release proudly announced that earlier that month, the Company had held its first end-of-Phase II meeting with the U.S. Food and Drug Administration ("FDA") concerning approval of PV-10 to treat metastatic melanoma:

> Provectus Pharmaceuticals, Inc. … a development-stage oncology and dermatology biopharmaceutical company, announced today that it has held an end-of-Phase 2 meeting with the U.S. Food and Drug Administration (FDA) to seek consensus on clinical program scope and endpoints for licensure of PV-10 for metastatic melanoma. The meeting was held at the Agency's White Oak Campus in Silver Spring, MD.
>
> Craig Dees, Ph.D., CEO of Provectus said, "This meeting provided an opportunity to thoroughly review the clinical data we have amassed through our Phase 1 and Phase 2 studies with PV-10. As expected, the meeting was fruitful and provided a forum for discussion of appropriate endpoints for assessment of clinical benefit of PV-10 in melanoma patients and for definition of the pathway leading to licensure."

> Dr. Dees continued: "Based on consultation with senior Agency officials during this meeting, we expect to hold a second end-of-Phase 2 meeting in the coming months to finalize design of a pivotal Phase 3 randomized controlled study suitable for Special Protocol Assessment (SPA)."
>
> Dr. Dees concluded, "We are fortunate that our capital resources afford flexibility to consider pursuing both the conventional Phase 3 pathway, as well as an accelerated route to licensure. While we believe the Phase 3 with an SPA represents an industry standard path to approval, we believe the door may still be open for accelerated approval."

6. Over the next few years, Provectus started early trials for PV-10 and PH-10 to treat other conditions, presented the results of its Phase II metastatic melanoma trials at numerous medical conferences, began the approval process for the two drugs in other countries, and sought to attract investors and raise funds. Neither Phase III studies nor accelerated routes to FDA approval for PV-10 to treat metastatic melanoma were actively pursued between 2010 and 2013. During the same time frame, major pharmaceutical companies keenly focused their attention on obtaining FDA approval for drugs to treat metastatic melanoma. Between 2011 and mid-2013, the FDA approved a number of new drugs to treat melanoma, including Yervoy (ipilimumab), Zelboraf (vemurafenib), Tafinlar (dabrafenib), and Mekinist (trametinib).

7. Both PV-10 and PH-10 are derived from Rose Bengal, a sodium salt first used as a herbal remedy by the medical community in the late 1800s. Rose Bengal acts as a stain which can be and has been used as a disease diagnostic for over 50 years; the stain enables the identification of and distinction between living and dead cells. It has been most commonly used in eye drops to stain damaged conjunctival and corneal cells, thereby allowing identification of damaged areas of the eye. It also has been used to diagnose liver cancer and eye cancer.

8. Because Rose Bengal was a familiar compound, safely used as a medical stain for years, Defendants represented that PV-10 could be an important new treatment for cancer. For example, as set forth in the Company's 2013 10-K:

> We believe our prescription drug candidate **PV-10 may afford competitive advantage compared to currently available options for the treatment of certain types of cancer**. We are developing PV-10, a sterile injectable form of rose bengal disodium (Rose Bengal), for **direct injection into tumors**. It is an immuno-chemoablative agent that when injected intralesionally is tantamount to an "in situ" vaccination following acute and durable necrosis of diseased tissue. Because PV-10 is retained in diseased or damaged tissue but quickly dissipates from healthy tissue, we believe we can develop therapies that confine treatment to cancerous tissue and reduce collateral impact on healthy tissue. (Emphasis added.)

9. On December 16, 2013, the FDA and Provectus held a meeting regarding the road to FDA approval of PV-10. According to a press release issued by the Company on December 18, 2013, and filed as an exhibit to SEC Form 8-K of the same date, "[t]he purpose of the meeting was to determine which of the available paths that Provectus' novel oncology drug PV-10 will take in pursuit of FDA approval and commercialization." In the release, Defendant Craig Dees is quoted as saying: "[t]his meeting with the FDA is a significant step forward in establishing a pathway to initial U.S. approval of PV-10 for the treatment of melanoma." He went on to state that "[t]here are different possible routes to approval of PV-10 such as a *breakthrough therapy designation* or accelerated approval…." The press release also reminded investors that "Provectus has recently completed Phase 2 trials of PV-10 as a therapy for metastatic melanoma." (Emphasis added.)

10. During the time between the end-of-Phase II meetings Provectus had with the FDA in 2010, and late 2013, a new method of accelerated consideration of drug candidates came into existence. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act became law. One of its provisions allowed the FDA to accelerate the approval process for a drug considered to be a "breakthrough therapy." To obtain a "breakthrough therapy designation" from the FDA, a proponent must submit "preliminary clinical evidence that demonstrates the

drug may have substantial improvement on at least one clinically significant endpoint over available therapy."

11. Although Defendants' December 18, 2013, press release optimistically discussed the possibility of applying for a "breakthrough therapy designation" ("BTD") – which could shorten the approval timeline for PV-10 to less than a year (from receipt of such a designation) because costly Phase III testing could be bypassed[1] – they failed to disclose, however, that at the December 16, 2013, meeting *and a number of earlier meetings with the FDA starting in April 2010*, the FDA had already communicated to Provectus "concerns regarding the development program and provided advice regarding the type of data that should be systematically collected to determine the clinical benefit(s)" of PV-10, and that the data collected during the Phase II trials failed to address those concerns such that Provectus could not implement the advice provided by the FDA at the most recent meeting – a fact which was later admitted by Defendant Wachter.

12. Specifically, as set forth in further detail herein, Defendants ignored the FDA's express requirement that secondary relief endpoints, *e.g.*, pain, infection and significant bleeding, needed to be demonstrated to show clinical benefit, and that tumor shrinkage *per se* would not be sufficient to meet the BTD requirement that the new drug show substantial improvement over existing therapies.

13. Because Defendants sought to spark investment interest with the news about the Type C meeting, they issued a press release on January 15, 2014, just to announce that the minutes of the meeting had not yet been received (because Provectus had provided comments to the FDA).

[1] *See, e.g.*, "FDA's New Breakthrough Therapy Designation: What Does it Mean for Pricing and Market Access," OBR GREEN (Sept. 2013 ed.), at Figure 2 (BTD eliminated an average of 30.5 months devoted to Phase III trials and slightly shortened the New Drug Approval ("NDA") process.) *http://obroncology.com/obrgreen/print/FDAs-New-Breakthrough-Therapy-Designation*

14. On January 21, 2014, an analyst report by Small Cap Street set a price target of $62.04 per share. After discussing the regulatory history of PV-10 and results reported at the European Cancer Organization meeting, the author concluded: "Given the longstanding safety record of the PV-10 drug, its short 30 minute half-life, and its ability to shrink or eliminate treated and untreated tumors and their metastases, there does not seem to be any downside to the drug's approval by the FDA." The author further cited an interview with Defendant Culpepper in which he indicated that Provectus did not intend to market PV-10 itself and that Provectus was looking to be purchased by a larger company. Should PV-10 soon achieve BTD status, this would portend a lucrative buy-out in the near future. This report caused a run-up in Provectus's share price of more than a dollar, from a close of $2.93 on Friday, January 17, 2014, to $3.99 on Tuesday January 21, 2014 (the first trading day after the Martin Luther King Jr. Day holiday).

15. The next day, a PRNewswire press release was issued, for the sole purpose of alerting and linking readers to the report. As a result, Provectus's shares continued to rise, to close at $5.22 on January 22, 2014. On January 23, 2014, shares opened higher following after-hours trading, at $5.60, and reached a high of $6.03.

16. Late in the morning of January 23, 2014, Adam Feuerstein ("Feuerstein") published a highly-critical article on *TheStreet.com* entitled "The Obsolescence of Provectus' Skin Cancer Drug Means Current Speculative Run Ends Badly." Therein, Feuerstein asserted that Provectus management has misled investors about the prospects for PV-10 and questioned why Provectus had not yet started its long-promised Phase III randomized controlled trial of PV-10 suitable for a Special Protocol Assessment after completing its Phase II study in 2010. Feuerstein theorized that PV-10 may be obsolete in light of new skin cancer drugs recently approved and/or in advanced development by large pharmaceutical companies. Feuerstein also

suggested that because of these significant advances, Provectus would have a difficult time enrolling patients for its own Phase III trials – even speculating that the FDA told Provectus not to bother trying.

17. Sometime later that day, Provectus responded directly to Feuerstein, submitting a "Letter to the Editor" of *TheStreet.com* signed by Defendant Peter Culpepper. The letter attempted to assuage investors' fears by directly disputing the concerns raised by Feuerstein in his article. The letter insisted that Mr. Feuerstein's article contained "several inaccuracies and omissions" which Mr. Culpepper's letter purports to address. The letter also cited several instances where Feuerstein purportedly cherry-picked potentially negative information in the market while ignoring positive information the Company provided him. After the market closed on January 23, 2014, the letter was filed with the SEC as an exhibit to a Form 8-K.

18. Reacting to Feuerstein's critique the market punished Provectus's stock price; it plummeted $3.35 per share to close at $1.87 per share on January 23, 2014, a decline of nearly 64% on heavy volume of 30.5 million shares.

19. To rebuild investor confidence and interest in the wake of Feuerstein's attack, Defendants went on the offensive on January 24, 2014, announcing that it planned to seek a BTD for PV-10, for the treatment of "locally advanced cutaneous melanoma." Without expressly stating that it was changing directions from its prior focus on metastatic melanoma, Provectus touted that it was seeking BTD for "the first local agent for recurrent locoregionally advanced melanoma …, [a] troublesome, disfiguring disease that can persist for many years before presenting at distant sites."

20. Defendants explained that the December 16, 2013, meeting and the official minutes therefrom "provided valuable guidance on a number of issues surrounding the approval

path of PV-10." Specifically, (a) "the Agency agreed with Provectus that treatment of cutaneous and subcutaneous tumors in patients with locally advanced cutaneous melanoma (i.e., recurrent, in-transit or satellite melanoma that has not yet spread from the skin to distant sites) could provide clinical benefit to such patients, *particularly if the measured objective responses in patients' disease correlated to a demonstrated treatment effect on one or more symptoms of their disease (e.g., pain, infection or significant bleeding*)"; (b) "The Agency agreed to work with Provectus to quantify symptom control in this patient population"; (c) "In reference to discussions on the potential for breakthrough therapy designation, 'FDA advised Provectus to provide objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions.'" (Emphasis added.)

21. This press release was false and materially misleading because it led investors to believe that with a redirected focus to recurrent localized tumors as opposed to metastatic melanoma the FDA would look more favorably on PV-10, Phase III trials might be avoided, and/or approval might occur less than a year from submission of the application for BTD. However, the opposite was likely true: Because the targeted indication was now for tumors that recurred without metastasizing, the disease was, according to Provectus, "troublesome and disfiguring" rather than life-threatening; therefore, prolonging of life, the usual gold standard for effectiveness, did not apply. This made symptom relief beyond that provided by existing therapies the objective endpoint for success needed to obtain BTD approval. As later admitted by Dr. Wachter, at the time they issued the press release, Defendants knew that Provectus's Phase II studies focused on treating metastatic melanoma; therefore, Provectus did not collect – and could

not provide the FDA with – evidence of symptom control in the treatment of recurrent localized tumors.

22. In combination with Mr. Culpepper's "Letter to the Editor," the announcement stopped Provectus's slide and caused its share price to close nearly 14% higher than on January 23, 2014, at $2.13 on January 24, 2014, on heavy trading volume.

23. On March 24, 2014, Provectus issued a press release indicating that it had filed for a BTD application for PV-10 and that the FDA would most likely respond in 60 days.

24. On May 20, 2014, just as investors were waiting for news about the FDA's decision, Feuerstein noted in another article published on *TheStreet.com* that Provectus had improperly described PV-10 as a "breakthrough" drug for skin cancer on its website prior to the FDA designating the drug as such. The description of the drug on the Company's website was immediately amended to "investigational."

25. On May 21, 2014, a *SeekingAlpha.com* contributor attacked Provectus as a complete fraud and set a price target of zero. This publication highlighted the failure of Provectus to commence a Phase III trial of PV-10, despite the expiration of patents in 2016 and a cash burn of $150 million. The publication further alleged that the Company was tied to a stock promotion firm, Small Cap Street, whose other stock recommendations were for companies whose trading had been recently halted by the SEC, and Provectus's management has paid itself more than $49 million since the Company's inception (mostly to four individuals) by repeatedly raising funds and diluting shareholder equity. Finally, the author speculated that PV-10's BTD application had been denied.

26. As Defendants did when Feuerstein issued his scathing critique, the same day (Wednesday, May 21, 2014), Provectus issued a press release refuting supposed inaccuracies in

the blog on *SeekingAlpha.com.* In the release, Defendants specifically asserted that PV-10 had not failed to achieve Breakthrough Therapy Designation – rather, the Company was awaiting a decision from the FDA, and that its most important patents were not about to expire. Additionally, Provectus denied any affiliation with stock promoters.

27. On this news, Provectus's stock price dropped $0.46 per share from the prior day's close, to close at $2.24 per share on May 21, 2014, a one-day decline of over 17% on very heavy volume.

28. The next day, an article by Sean Williams, published on *TheMotleyFool.com* discussed the attack and response the previous day. The article then went on to advise investors not to purchase Provectus shares until PV-10 achieves BTD status and finds a partner or the Phase III trials are up and running. The article questioned the delay since the Company's report of top-line data from the Phase II trial in October 2012. On this less-than-positive report, Provectus's stock price dropped an additional $0.22 per share to close at $2.02 per share on May 22, 2014, a one-day decline of nearly 10%, again on heavy volume. This marked a two-day decline of $0.68 – translating to a loss of approximately 25% of the stock's value. The decline may have been higher but for Defendants' continued attempts to falsely re-assure investors. Ironically, Provectus management had rung the opening bell on the NYSE that morning.

29. On Friday, May 23, 2014, Provectus shocked the market, issuing a press release (which it also filed as an exhibit to SEC Form 8-K, dated May 21, 2014, but filed May 23, 2014) announcing that "on the afternoon of May 21, 2014" Provectus received a notice from the FDA dated May 16, 2014 – *one week prior to this disclosure* – denying the Company's request for Breakthrough Therapy Designation for PV-10. In the letter, the FDA stated that it had previously expressed the concerns set forth therein "at the April 8, 2010, March 7, 2011, and

October 18, 2011, end-of-Phase 2 meetings and the December 16, 2013 General Guidance teleconference." Specifically, the FDA "provided advice regarding the type of data that should be systematically collected to investigate the clinical benefit(s) of an intratumoral treatment." The letter revealed that during the Class Period, Defendants' statements about the FDA's advice mislead investors into believing that this data would be provided in the BTD application – when Defendants knew it could not be provided.

30. The Company also held a conference call on the afternoon of Friday May 23, 2014, to address investors' questions regarding PV-10, the BTD denial, and the Company's planned next steps regarding seeking FDA approval for PV-10. The conference call contained a series of stunning admissions concerning Defendants' knowledge that the information from its Phase II trials would not be sufficient to satisfy the FDA's requirement of objective, demonstrated treatment effects on one or more symptoms. First, Provectus's Chief Technical Officer, Dr. Eric Wachter, frankly admitted that the BTD application had been doomed from the start:

> **[W]e had lengthy discussions with the Agency in our December 2013 meeting,** uh, on the outcome in these patients, discussed the, uh, the objective response parameters that I've just outlined.
>
> **And the Agency asked us for, uh, additional evidence showing that those responses correlated with, uh, symptomatic improvement in the patients. That is, improvement in things such as pain, lesions, bleeding in the lesions, infection in the lesions,** and so on.
>
> **Uh, unfortunately**, the phase two study did not require patients to have baseline symptoms in these types outside, uh, the existence of biopsy proven melanoma for enrollment.
>
> And **we did not design the study to collect the type of detailed information on symptoms that might be ideal for showing that correlation.** (Emphasis added.)

Later, Dr. Wachter admitted Defendants' conceit:

> **"[I]t was a measured risk, uh, submitting the application**. But again as I mentioned earlier, uh, **our logic seemed clearer that if we were making the patients' tumors disappear** in 50 percent of the patients that was a very large effect size, and **that was tantamount to making any symptoms that they might have been suffering from the tumor burden, uh, disappear**." (Emphasis added.)

But, as Defendants repeatedly stated during the Class Period, the FDA expressly told defendants to provide evidence of secondary endpoint objective responses in terms of pain, infection, and significant bleeding. Defendants never informed investors that they submitted the BTD application without providing such evidence, and, in fact, misled investors to believe that they had done so.

31. When one investor aptly described what Defendants had done and asked if his assessment was correct, Dr. Wachter could not disagree:

> The first question, I read the FDA letter a number of times. And I get the sense that we're like the star pupil in the class. And the teacher says you gotta do the exam this way to pass. And we're not listening.
>
> The paragraph on page two says kind of we told you guys on four occasions, and they give us the dates, of the kind of data we need. It just feels, and maybe I'm a layperson here, Eric. So, forgive my ignorance.
>
> **It kind of feels they keep telling us to do it in this way. And we feel as though we're smarter and not listening, saying, no, we can do it another way.** Is that misplaced, that observation or without foundation?
>
> **Wachter: Um, I can understand that as an interpretation of the situation.** Um, what I'd like to do is turn to, uh, another one of these talking points. I'm sorry.

(Emphasis added.)

32. On May 23, 2014, trading in Provectus stock was halted at $2.02 per share, "pending news." The stock resumed trading on or about May 27, 2014, after the close of the Class Period, closing at $0.75 per share.

III. JURISDICTION AND VENUE

33. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Securities Exchange Act (15 U.S.C. §§78j(b) and 78t(a)) and Rule 10b-5 (17 C.F.R. §240.10 b-5) promulgated thereunder by the SEC.

34. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §1331 and §27 of the Securities Exchange Act (15 U.S.C. §78aa).

35. Venue is proper in this District pursuant to §27 of the Securities Exchange Act (15 U.S.C. §78aa(c)) and 28 U.S.C. §1391(b), as Provectus operates in this District and many of the acts and practices complained of herein, including the preparation and dissemination of materially false and misleading information, occurred in substantial part in this District.

36. In connection with the acts alleged in this complaint, defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, and the facilities of the New York Stock Exchange ("NYSE"), a national securities market.

IV. PARTIES

37. Lead Plaintiff Fawwaz Hamati purchased Provectus securities during the Class Period as set forth in the certification previously filed with this Court and incorporated herein by reference, and was damaged thereby as the result of Defendants' wrongdoing as alleged in this complaint.

38. Defendant Provectus is a Knoxville, Tennessee-based pharmaceutical company specializing in the development of oncology and dermatology therapies.

39. Defendant H. Craig Dees ("Dees") is, and at all relevant times was, Chief Executive Officer ("CEO") and Chairman of the Board of Provectus. During the Class Period, Dees communicated with the FDA regarding the approval status for PV-10. Dees also

participated in the issuance of, was quoted in, signed, and/or certified as accurate the Company's public statements and periodic filings with the SEC, including the 2013 Form 10-K, and all Form 8-Ks and Form 10-Qs filed during the Class Period. As CEO, Dees certified the accuracy of the Company's SEC filings as required under the Sarbanes-Oxley Act of 2002 ("SOX").

40. Defendant Timothy C. Scott ("Scott") is, and at all relevant times was, President and a director of Provectus. Provectus's 2013 Form 10-K describes Scott as one of Provectus's four key employees, explaining further that "[i]n addition to their responsibilities for management of our overall business strategy, Drs. Dees, Scott and Wachter are our chief researchers in the fields in which we are developing and planning to develop our prescription drug and other product candidates, and our OTC products." Defendant Scott signed the 2013 10-K on behalf of the Company.

41. Defendant Peter R. Culpepper ("Culpepper") is, and at all relevant times was, Chief Financial Officer ("CFO") of Provectus. Defendant Culpepper also served as Chief Operating Officer ("COO") of Provectus during the Class Period. During the Class Period, Culpepper communicated with the FDA regarding the approval status for PV-10. During the Class Period, Culpepper also participated in the issuance of, was quoted in, signed, and/or certified as accurate the Company's public statements and periodic filings with the SEC, including the 2013 Form 10-K, and all Form 8-Ks and Form 10-Qs filed during the Class Period. As CFO, Culpepper certified the accuracy of the Company's SEC filings as required under the Sarbanes-Oxley Act of 2002 ("SOX"). Culpepper also participated in the Company's May 23, 2014, investor conference call.

42. Defendant Dr. Eric Wachter ("Wachter") is, and at all relevant times was, Chief Technical Officer ("CTO") of Provectus. During the Class Period, Wachter communicated with

the FDA regarding the approval status for PV-10. Wachter was also responsible for the Company's public statements, including press releases issued during the Class Period, and participated in the Company's May 23, 2014, investor conference call.

43. The defendants named above in ¶¶39-42 are referred to herein as the "Individual Defendants." The Individual Defendants and the Company, together, are referred to collectively herein as "Defendants."

44. The Individual Defendants, because of their positions with the Company, possessed the power and authority to control the contents of the Company's public statements. Each defendant was provided with copies of the Company's SEC filings and press releases alleged herein to be false and/or misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of these defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading. The Individual Defendants are liable for the false statements pleaded herein, as those statements were each "group-published" information, the result of the collective actions of the Individual Defendants.

V. OVERVIEW OF FDA REVIEW AND APPROVAL PROCESS; BREAKTHROUGH THERAPY DESIGNATION

45. The FDA regulates, among other things, research and development activities and the testing, manufacturing, quality control, safety, effectiveness, labeling, storage, record keeping, approval, advertising and promotion of proposed prescription drug treatments, such as PV-10. FDA approval of each proposed indication was a prerequisite to Provectus's ability market and sell PV-10 in the United States.

46. The regulatory process required by the FDA, through which drugs (such as PV-10) or device products must pass successfully before they may be marketed and sold to consumers in the U.S., generally involves the following: (i) Preclinical laboratory and animal testing; (ii) submission of an application that must become effective before clinical trials may begin; (iii) adequate and well-controlled human clinical trials to establish the safety and efficacy of the product for its intended indication (conducted in "Phase I," "Phase II," and "Phase III" trials); and, finally (iv) FDA approval to market a product for a specific indication.

47. The Food and Drug Administration Safety and Innovation Act (the "FDASIA") was signed into law on July 9, 2012, creating the "breakthrough therapy" designation ("BTD" or "Breakthrough Therapy Designation") for important drugs and therapies in early development. Breakthrough Therapy Designation provides a pharmaceutical company with a number of advantages, including working closely with the FDA to streamline development, and – particularly significant in this case – an expedited FDA review and approval process.

48. Defendants described Breakthrough Therapy Designation as follows in the Company's 2013 10-K:

> With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, the Food and Drug Administration (FDA) was given powerful expedited tools to speed patient access to innovative medicines for serious or life-threatening conditions. FDASIA initiatives such as **breakthrough therapy designation** are **designed to accelerate approval for new drugs that show preliminary clinical evidence of a large treatment effect**. A key feature of BTD authorizes the FDA to take steps to ensure that the design of the clinical trials are as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment. Requests for BTD are reviewed and granted or rejected within 60 days of receipt. As we have previously reported, based on rapid tumor destruction in a positive Phase 2 trial in melanoma patients receiving PV-10 (protocol PV-10-MM-02), we sought input from the FDA regarding our current development plan. FDA guidance encourages sponsors to seek such advice prior to formal request for designation. (Emphasis added.)

49. Under the FDASIA, the FDA may award Breakthrough Therapy Designation status to drugs in early development which have been shown to: (i) treat a serious or life-threatening medical condition; and (ii) provide a substantial improvement over currently existing and available drugs or therapies.

VI. DEFENDANTS' DEVELOPMENT OF PV-10 AND ITS HISTORY OF FDA REVIEW; ADVANCES IN MELANOMA TREATMENT BETWEEN 2010 AND 2013

50. As stated in Provectus's SEC filings, PV-10 is a "sterile, injectable form of rose bengal disodim (Rose Bengal)." Rose Bengal is a stain commonly used as a diagnostic tool, most commonly to diagnose eye disease. At all relevant times, Defendants insisted that PV-10 is different from regular, commercial-grade Rose Bengal that had been used diagnostically within the medical community for decades.

51. Provectus spent years developing PV-10 as a treatment for metastatic melanoma and other diseases. According to Defendants, when injected directly into skin cancer lesions, PV-10 supposedly kills the tumor cells. Defendants also claimed the drug had an immune system-boosting effect, supposedly also killing cancer cells in "bystander lesions" not directly injected with PV-10.

52. In 2010, Defendants conducted a single, open-label Phase II study of PV-10 in 80 metastatic melanoma patients. The study reported a 51% overall response rate in lesions that were directly injected with PV-10. Thirty-three percent of patients also showed some tumor shrinkage in bystander lesions. Because PV-10's immunotherapeutic effects were being tested, only 28 patients had all of their tumors injected with PV-10. Provectus completed the PV-10 Phase II study in 2010, and the Company reported results at various medical meetings in subsequent years. Few, if anyone, in the medical community or on Wall Street appeared to take notice of the PV-10 Phase II findings.

53. For almost two years following the completion of the Phase II study in 2010, Provectus promised investors that a randomized, controlled Phase III study of PV-10 to treat metastatic melanoma would soon commence. According to the Company's SEC filings, Provectus met with the FDA in April 2010, March 2011, and October 2011, purportedly to help design this registration-quality study.

54. In a letter dated April 24, 2012, Provectus CEO Craig Dees told shareholders the following:

> During 2011 we held our second and third meetings with the FDA to discuss the design of a pivotal Phase 3 randomized controlled trial ("RCT") suitable for Special Protocol Assessment ("SPA"). **In December [2011] the FDA provided us further guidance regarding the submission of our Phase 3 protocol for review, notifying us that they did not require an additional end-of-Phase 2 meeting. Using the recommendations that we received from senior FDA officials regarding patient population and primary endpoint, we are requesting SPA review of our protocol**. While the review process could occur in as little as 45 days from the date of submission, we expect it will be an iterative process, and thus, more time may be required to work with the FDA on a study design agreement. **This, we believe, represents a major step for our company, probably the most significant achievement yet, in our pathway to approval for PV-10**. (Emphasis added.)

55. Defendants did not thereafter proceed to Phase III testing of PV-10, however. Moreover, Provectus did not submit its BTD application to the FDA until March 21, 2014 – approximately two years after the above-cited letter (and 20 months after it could first apply for BTD status).

56. In fact, Provectus was unsuccessful in securing a development partner for PV-10 despite much effort and promises by management. Instead, management raised money through multiple rounds of financing. By March 7, 2014, the number of shares outstanding was an incredible 172,450,253, despite the fact that Provectus admits that it has never generated any substantial revenues.

57. While Provectus spent a few years looking for well-funded partners to develop its drug candidates, and presented its PV-10 Phase II metastatic melanoma results (and the results of other testing) at medical conferences all over the word, Bristol-Myers Squibb's ("BMS") cancer immunotherapy, the so-called "checkpoint inhibitor" Yervoy, was approved for melanoma treatment in 2011. Drugs that target specific skin cancer mutations, known as "single transduction inhibitors" from Roche (Zelboraf) and GlaxoSmithKline (Mekinist, Tafinlar) were approved thereafter.

58. In September 2013, researchers at the National Cancer Institute at the National Institutes of Health announced that they had identified seven potential immunotherapy targets for the treatment of melanoma. Specifically, their research revealed that seven genes were overexpressed in a large number of tumor samples.

59. During the Class Period, a new crop of even more powerful immunotherapy treatments, then under development by BMS (approved as under the trade name Opdivo in 2014), Merck (approved under the trade name Keytruda in 2014), Roche and others became the focus of significant attention by the medical and investor communities. (Opdivo and Keytruda had been granted BTD by the FDA.) Pharmaceutical companies were making rapid progress with drug combinations and/or use of the newer immunotherapies in conjunction with older therapies, *e.g.,* Roche's Zelobraf was being tested in conjunction with Exelixis's cobimetinib.

60. In sum, PV-10 was quickly being marginalized and, with new multiple new drugs being approved, either alone or in combination, was facing mounting hurdles to being able to make the showing of a "substantial improvement over currently existing and available drugs or therapies" required to achieve Breakthrough Therapy Designation.

61. Up until just prior to the Class Period – at which point Defendants started

artificially inflating the Company's share price through their false and misleading statements regarding PV-10's FDA approval track and Breakthrough Therapy Designation of PV-10 – which inflation Defendants continued to generate and maintain throughout much of the Class Period – Provectus shares traded for less than $1.00.

VII. DEFENDANTS' MATERIAL MISREPRESENTATIONS AND OMISSIONS DURING THE CLASS PERIOD

62. Defendants are liable for making false statements and/or failing to disclose adverse facts known to them about Provectus's business, specifically regarding its key drug, PV-10, and its path to FDA approval.

63. Defendants' fraudulent scheme and course of business that operated as a fraud or deceit on purchasers of Provectus securities was a success, as it: (i) deceived the investing public regarding Provectus's prospects and business; (ii) artificially inflated the prices of Provectus securities during the Class Period; and (iii) caused Plaintiff and other members of the Class to purchase Provectus securities at inflated prices during the Class Period.

64. On December 17, 2013, Provectus issued a press release entitled "Provectus Announces Name Change to Provectus Biopharmaceuticals, Inc. and Reincorporates in Delaware." The December 17, 2013, press release was attached as an exhibit to SEC Form 8-K, signed by Defendant Culpepper, and filed on the same date. The press release was a blatant attempt to take advantage of investor interest in recent drug approvals and research findings with respect to immunotherapies to treat melanoma. In this release, Defendant Dees stated in part:

> We felt that a change in the corporate name to 'Provectus Biopharmaceuticals, Inc.,' better communicates to the public the current and future nature of the Company's business operations and enables the Company to better implement its business plan. **In particular, the Company's drug product candidates (pharmaceutical preparations) in both the oncology and dermatology therapeutic areas have either shown, or are expected to show through independent research, a capacity to harness the immune system of those patients treated**. **For oncology patients [*i.e.*, for PV-10], this means using**

> **their bodies' own disease-fighting capabilities to aid in reducing their tumor burden in various cancer indications**. For dermatology patients, these same immune-system abilities can reduce the inflammation of their various inflammatory dermatoses. **Both of these approaches to treat disease relate to properly utilizing the patient's biologic or immune system and not just the direct treatment of his or her disease**. Thus, 'biopharmaceutical' is a more apt term. The new name does not affect our business, operations, reporting requirements or stock price but will require a new CUSIP. (Emphasis added.)

65. The December 17, 2013, press release was materially false and/or misleading because it misrepresented the prospects for PV-10 and/or omitted material information known to Defendants. For example, Defendants knew at the time this statement was made that the statement "[f]or oncology patients [*i.e.*, for PV-10], this means using their bodies' own disease-fighting capabilities to aid in reducing their tumor burden in various cancer indications" was materially false and misleading because PV-10 had not been satisfactorily proven to successfully "harness" oncology patients' "own disease-fighting capabilities to aid in reducing their tumor burden in various cancer indications."

66. The statement was materially misleading because it implied that PV-10's Phase II findings of any objective response in untreated, bystander tumors was due to PV-10's ability to trigger a patient's immune system to systemically attack the cancer in untreated locations. If Defendants had sufficient data to demonstrate this, they would have found a funding partner or another drug company to work with to develop PV-10. Instead, by renaming the Company and talking up PV-10 as a serious immunotherapy candidate, they were trying to take advantage of recent news surrounding the potential for new immunotherapies to treat melanoma.

67. The statement was also materially misleading as it came a mere day after the December 16, 2013, meeting with the FDA, during which the FDA communicated its concerns to Defendants regarding the development program for PV-10. As Defendants later explained, when Provectus submitted its BTD application, at the December 16, 2013, meeting the FDA

"expressed willingness to work with Provectus toward initial approval for the novel investigational oncology drug PV-10 in locally advanced cutaneous melanoma." Specifically, the FDA asked for submission of data "in a cohort of patients that received PV-10 to all existing lesions." Consequently, Defendants knew that their focus for PV-10 approval was shifting away from treating systemic, metastatic melanoma to the use of PV-10 injections as a new treatment for recurring, local tumors. Therefore, with respect to the Company's most-promising drug, the name change – and the stated reasons therefor – were largely irrelevant, and just used by Defendants to take advantage of investor interest in the many new immunotherapies for melanoma and the research suggesting which gene mutations to target next.

68. On December 18, 2013, Provectus issued a press release entitled "Provectus Type C Meeting with FDA Oncology Division held December 16, 2013. *OFFICIAL MINUTES EXPECTED BY JANUARY 15, 2014.*" The release was filed as an exhibit to SEC Form 8-K, also dated December 18, 2013, and signed by Defendant Culpepper. The release stated in part:

> Provectus Pharmaceuticals, Inc., a development-stage oncology and dermatology biopharmaceutical company, today announced that it **held a Type C meeting with the FDA's Division of Oncology Products 2 on December 16, 2013**. **The purpose of the meeting was to determine which of the available paths that Provectus' novel oncology drug PV-10 will take in pursuit of FDA approval and commercialization**.
>
> Under FDA rules, the agency should issue official minutes to the Company within 30 days after such a meeting; in this case by January 15, 2014. The minutes will clarify the available regulatory paths and, therefore, allow the Company to better estimate a time-line to commercialization of PV- 10.
>
> Chief Executive Officer Craig Dees, Ph.D. said, "**This meeting with the FDA is a significant step forward in establishing a pathway to initial U.S. approval of for the treatment of melanoma. There are different possible routes to approval of PV-10 such as a *breakthrough therapy designation or accelerated approval***, and each of these has different requirements and time lines. I appreciate that our shareholders are eager to receive as much information as possible, and while there is nothing more the Company can add until it has received the official meeting minutes, we wanted to provide this interim update. In addition, our discussions with several potential international licensing partners are not affected in any way." (Emphasis added.)

69. The December 18, 2013, press release attached to SEC Form 8-K also stated in part:

> Provectus Pharmaceuticals specializes in developing oncology and dermatology therapies. **Its novel oncology drug PV-10 is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, significantly reducing potential for systemic side effects. Its oncology focus is on melanoma, breast cancer and cancers of the liver.** The Company has received orphan drug designations from the FDA for its melanoma and hepatocellular carcinoma indications…. Provectus has recently completed Phase 2 trials of PV-10 as a therapy for metastatic melanoma…. (Emphasis added.)

70. The December 18, 2013, press release was materially false and/or misleading because it misrepresented the prospects for PV-10 and/or omitted material information known to Defendants:

a. Defendants misrepresented that PV-10's advantage was that it "significantly reduc[ed] potential for systemic side effects." During the December 16, 2013, meeting with the FDA, the FDA communicated significant concerns to Defendants regarding the development program for PV-10 and advised Defendants on the type of data that needed to be systematically collected in order to investigate the clinical benefits of PV-10 to treat melanoma. Specifically, the FDA had communicated to Defendants previously that secondary relief endpoints, *e.g.,* pain, infection and significant bleeding, would be required and that individual tumor shrinkage alone would not be sufficient. The statement was false when it was made because Defendants knew that insufficient data on the reduction of side effects was collected during the Phase II trials.

b. Defendants omitted the material concerns communicated by, and the advisement(s) offered by, the FDA from its public statement, and did not disclose that the Company would not or could not thereafter heed the FDA's advisement(s) because the Phase II PV-10 study had not been designed to capture the types of data end points required by the FDA.

71. These statements were made with scienter because Defendants attended the meeting with the FDA and knew about the insurmountable hurdles to obtaining BTD and/or FDA approval for PV-10, based upon the insufficiency of the data collected during the Phase II trials to demonstrate the secondary endpoints of symptom relief of pain, infection and/or significant bleeding required by the FDA.

72. In a subsequent SEC Form 8-K, dated January 15, 2014, and signed by Defendant Culpepper, Defendants announced that the Company had not yet received the final meeting minutes from the FDA, but explained that this was due to the give-and-take process between Provectus and the FDA. In particular, after the meeting:

> **[T]he Company took the opportunity to provide input into the documentation of meeting minute notes**. It is the opinion of the Company that this may have delayed the process of receiving the final meeting minute notes. Therefore, the Company will communicate further guidance from the FDA once the meeting minute notes have been received, which is expected shortly.
>
> It is also the Company's opinion that **the delay has no bearing on the FDA's decision regarding the efficacy of PV-10 but is rather a matter of observing governmental processes**. This delay also has no bearing on the Company's discussions and negotiations with parties outside the FDA's jurisdiction. (Emphasis added.)

73. The January 15, 2014, Form 8-K was materially misleading because Defendants gave the investors the false impression that they were working in collaboration with the FDA towards a establishing a pathway for approval of PV-10 to treat melanoma, while at the same time failing to disclose the concerns previously raised to them by the FDA "regarding the efficacy of PV-10" and regarding Defendants' development program for PV-10, specifically that secondary relief endpoints would be required to be shown in the study and that individual tumor shrinkage would not be sufficient. This materially-misleading statement was made with scienter because Defendants knew, at the time they made the statement, that Provectus had collected insufficient data during the Phase II trials to demonstrate the secondary endpoints of symptom

relief of pain, infection and/or significant bleeding required by the FDA – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*).

74. The statement was also materially misleading because it failed to disclose that regardless of their input into the meeting minutes, the Company could not thereafter heed the FDA's advisement(s) to be set forth in the final meeting minutes because of the insufficiency of the data collected during the Phase II trials to demonstrate the secondary endpoints of symptom relief of pain, infection and/or significant bleeding required by the FDA. This materially misleading statement was made with scienter because Defendants knew, at the time they made the statement, that Provectus had collected insufficient data during the Phase II trials to demonstrate the secondary endpoints of symptom relief of pain, infection and/or significant bleeding required by the FDA – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*).

75. On Tuesday, January 21, 2014, a company called Small Cap Street ("SCS") issued an analyst report concerning Provectus on its Website, SmallCapStreet.com. Although its disclaimer indicated that the company was "in the business of marketing and advertising companies for monetary compensation," SCS also stated: "SmallCapStreet.com has not been compensated for the mention of PVCT." In addition to setting an astonishing price target of $62.04, highlights of the report include:

> The Phase II results indicate that the drug acts as chemical means of "knife-less surgery" eliminating the cancerous but sparing normal tissue. In the process, the data show that PV-10 acts to sensitize the patient's immune system to the cancer so that the patients' own defenses can attack and defeat cancerous tumors. This has been repeatedly demonstrated by purposely treating only some of the patient's tumors, and noting the significant effect on the lesions that had not been treated with PV-10.
>
> In the latest trials report, at the European Cancer Organization (ECCO) Meeting, the elderly Melanoma patients that were treated had already failed a median of six (6) other types of treatments. Given the longstanding safety record of the PV-10 drug, its short 30 minute half-life, and its ability to shrink or eliminate treated and

> untreated tumors and their metastases, there does not seem to be any downside to the drug's approval by the FDA.
>
> * * *
>
> PVCT's Management has announced in the past that they plan to sell the company and do not plan on bringing their drugs to market by themselves. In the Wall Street Transcript interview, Peter Culpepper, COO and CFO asserted that, given the Market opportunity, he expects a deal to exceed the $2.9 Billion up-front payment by Celgene (CELG) for Abraxis. In addition, he expects to get post-sale milestone payments with shareholders benefiting via a "contingency value right", as happened in the Abraxis deal.
>
> The expected buyout is expected to bring 1500% returns, in the Biotech industry this kind of ultimate return does happen. The research and Compassionate Use Program results are the reason that the CFO has the confidence to sound so upbeat about PVCT's valuation. PV-10's effects on solid tumors is likely to allow it to address a huge market in a wide variety of cancers. Based upon Provectus' own Market, market share, and other data, we have estimated these opportunities to find the underlying numbers behind the confidence.[2]

76. On this news, Provectus's stock price soared, from a close of $2.93 on Friday, January 17, 2014, to a closing price of $3.99 per share.

77. Just in case investors missed the mention the previous day on SmallCapStreet.com, on January 22, 2014, a wider audience for the report was created when a PRNewswire press release was issued solely for the purpose of directing investors to the "full analyst report."[3] Provectus's stock price reached its Class Period closing high of $5.22 per share that day, on heavy trading.

78. Although Provectus's share price continued to rise in after-hours trading, opening on January 23, 2014, at $5.60 per share, and even rose to as much as $6.03 a share, at 11:26 a.m. that morning, Adam Feuerstein published an article on *TheStreet.com* entitled "The

[2]Quoting from "Provectus Pharmaceuticals, Inc. Analyst Research Report by Osman Ghani, Chartered Financial Analyst" (located at http://smallcapstreet.com/pvtc/, viewed April 1, 2014).

[3]http://www.prnewswire.com/news-releases/provectus-pharmaceuticals-inc-analyst-research-report-241447641.html (last visited April 1, 2014).

Obsolescence of Provectus' Skin Cancer Drug Means Current Speculative Run Ends Badly," which stated, in relevant part:

> A speculative mania has overtaken the Pink Sheet stock Provectus Biopharmaceuticals PVCT, triggered by Internet message board and Twitter rumors that FDA officials may sanction an accelerated approval filing of the company's long-delayed skin cancer drug PV -10.
>
> **Provectus' stock price has soared from 80 cents per share in December to almost $6 Thursday, doubling in price in the past seven days. Volume has been off the charts. The company's market capitalization now tops $1 billion** when warrants and options are included in the total share count - incredible for a bulletin board stock with less than 1% institutional investor ownership, according to S&P CapitalIQ.
>
> **Provectus is doing its part to feed the hungry maws of momentum traders, issuing a cryptic press release on Dec. 18 about a meeting with FDA to discuss "possible routes to approval of PV-10 such as breakthrough therapy designation or accelerated approval....**"
>
> The reasons for Provectus' sit-down with the FDA and the outcome of the meeting have not been disclosed. Provectus further fueled the speculative fervor by issuing an 8-K on Jan. 15 to announce that the receipt of official minutes from the FDA meeting were delayed.
>
> Provectus executives have now gone radio silent. Chief Operating Officer Peter Culpepper agreed to speak with me on Wednesday about PV-10 and the FDA meeting, but he cancelled a few hours before our scheduled phone call. Company spokesman Bill Gordon won't answer questions.
>
> The notion that FDA would bend over backwards to anoint PV-10 with breakthrough therapy designation or endorse a speedy approval pathway is fundamentally absurd, even by the lower standards of today's "anything goes" biotech investment climate.
>
> PV-10 is a diluted solution of Rose Bengal, a stain commonly used to diagnose eye disease. Rose Bengal can be purchased by the gallon from any chemical supply company, although Provectus claims PV-10 is purified Rose Bengal and somehow different.
>
> Provectus has spent years developing PV-10 as a treatment for metastatic melanoma and other diseases. When injected directly into skin cancer lesions, PV-10 supposedly kills the tumor cells. Provectus also claims the drug has an immune system-boosting effect which kills cancer cells in "bystander lesions" not directly injected with PV-10.
>
> The company conducted a single, open-label phase II study of PV-10 in 80 metastatic melanoma patients. The study reported a 51 % overall response rate in lesions that were directly injected with PV-10. Thirty-three percent of patients also showed some tumor shrinkage in bystander lesions.

> Provectus completed the PV-10 phase II study in 2010, and the company has reported results at various medical meetings in subsequent years. Few, if anyone, in the medical community or on Wall Street took special notice of the PV-10 melanoma data. Provectus has never been able to secure a development partner for PV-10 despite much effort and promises by management. Until very recently, Provectus shares traded for pennies.
>
> For almost two years, Provectus has been promising investors that a randomized, controlled phase III study of PV-10 in melanoma would be started shortly. To help design this registration-quality study, Provectus met with the FDA in April 2010, March 2011 and October 2011, according to the company's SEC filings.

79. In the article Feuerstein went on to question Provectus's delay in advancing to Phase III testing, and Defendants' silence regarding the same, noting that the failure to proceed to Phase III was likely related to a number of seemingly superior melanoma treatments had hit the marketplace since PV-10's Phase II study in 2010 and were currently being tested:

> Provectus is mum, but a likely explanation is that **the melanoma treatment landscape has changed dramatically since the PV-10 phase II results were first reported. Bristol-Myers Squibb's (BMY) cancer immunotherapy Yervoy was approved for melanoma in 2011. Drugs that target specific skin cancer mutations from Roche (ROG) and GlaxoSmithKline (GSK) have also been approved.**
>
> **Perhaps most significantly, a new crop of even more powerful cancer immunotherapies known as "checkpoint inhibitors" under development by Bristol, Merck (MRK), Roche and others have been the focus of significant attention by the medical and investor communities.**
>
> **All these changes for the better in the melanoma treatment landscape have further marginalized Provectus and PV-10.** The phase III study once proposed by the company two years ago probably couldn't be conducted today because patients are either being treated with already approved cancer immunotherapies like Yervoy or are eligible for the myriad of ongoing phase III studies involving the new checkpoint inhibitors.
>
> While Provectus shares explode higher on speculation that FDA wants to be more lenient with PV-10's approval pathway, the more sensible explanation is exactly the opposite. Given the huge advances in melanoma care today, FDA might be telling Provectus that it cannot proceed with the phase III study, as planned.
>
> FDA is also likely aware -- and concerned -- that a skin cancer drug very similar to PV-10 -- has already failed a large phase III study. Vical's Allovectin-7, which is also injected directly into tumors just like PV-10, failed to prolong survival in a randomized, controlled phase III study completed last year. Actually, patients

> treated with Allovectin-7 actually did worse than patients treated in the control arm.
>
> There is some precedent for accelerated approval of skin cancer drugs but the regulatory bar is still quite high. Earlier this month, FDA granted accelerated approval to the combination of two Glaxo drugs -- Tafinlar and Mekinist -- based on response rate data from a phase I/II study.
>
> However and importantly, both drugs were already approved separately for skin cancer before the accelerated approval for the combination was granted. Obviously, that's not the case for Provectus and PV-10. (Emphasis added.)

80. On January 23, 2014, Provectus wrote a "Letter to the Editor" responding directly to Feuerstein's article, adamantly denying Feuerstein's criticisms and attempting to quell investors' fears and boost confidence in Provectus, PV-10, and FDA approval. The Letter to the Editor was filed as an exhibit to SEC Form 8-K, also dated January 23, 2014 (filed after the market closed), and signed by Defendant Culpepper. The Letter to the Editor stated:

> To the Editor:
>
> We are writing in response to Adam Feuerstein's article, "The Obsolescence of Provectus' Skin Cancer Drug Means Current Speculative Run Ends Badly," published on TheStreet.com, January 23, 2014. In it there are several inaccuracies and omissions. For instance, he writes that "PV-10 is a diluted solution of Rose Bengal" that "can be purchased by the gallon from any chemical supply company." In fact, the opposite is true. PV-10 is a sterile, non-pyrogenic, high-purity concentrated solution of rose bengal manufactured specifically for Provectus to modern pharmaceutical standards, under current good manufacturing practice (cGMP), by specialty contract manufacturers. The investigational drug product undergoes comprehensive chemical and biological release testing prior to use in clinical trials. Neither the drug substance nor the drug product are available for third-party purchase from any commercial source and both are of markedly higher purity than commercial dye-grade material referenced by Mr. Feuerstein.
>
> Also, counter to Mr. Feuerstein's claim, the Company furnished a great deal of pertinent information through its independent press agent (not spokesperson) Bill Gordon that he failed to include in his article. For instance, Provectus CEO Craig Dees issued a formal letter on May 13, 2013 which included a "Regulatory Progress" section noting the ongoing process with the FDA and providing insights about options, delays and possibilities being explored. A link to that announcement is also available on the Provectus web site www.pvct.com.

We forwarded, as well, important scientific and medical announcements to Mr. Feuerstein, also omitted from his slanted coverage, regarding PV-10. One announcement, issued by Moffitt Cancer Center on August 22, 2013, highlights how early clinical trials show PV -10 can boost immune response in melanoma tumors, as well as the blood stream. Another, issued by our company on September 30, 2013, highlights important analyses of data from the completed Phase 2 study of intralesional PV-10 in metastatic melanoma as presented at the European Cancer Congress 2013 (ECCO 17 - ESMO-38 - ESTRO 32) in Amsterdam, The Netherlands. Both of these announcements are also available on the Provectus site for any readers interested in a more balanced view of the valuable work being done – and recognized – by Provectus on PV-10.

Perhaps most importantly, the company press release on December 18, 2013 clearly stated that our company held a Type C meeting (not an End of Phase 2 meeting) with the FDA on December 16, 2013 "to determine which of the available paths that Provectus' novel oncology drug PV-10 will take in pursuit of FDA approval and commercialization." **This press release also referenced an important new regulatory path, breakthrough therapy designation, that wasn't available in April 2012, the time at which Mr. Feuerstein implies the company went "mum" and after which our development program was purportedly static in the face of a rapidly changing commercial and regulatory climate.**

Mr. Feuerstein is selective in his choice of comparative metrics in melanoma, citing the 2013 failure of Allovectin-7 to prolong survival in Phase 3 testing while omitting mention of Phase 3 data on T-Vec, reported in a podium presentation at ASCO in June 2013, showing that this intralesional agent achieved its primary endpoint. While we won't attempt to address the myriad differences between these three agents, this cherry picking of negative data appears to be proffered to imply that PV-10 is destined for similar failure.

Finally, it is public knowledge that members of our corporate advisory board include Pfizer executives and other high profile life science professionals. These additions came as a result of recognition by members of the medical and pharmaceutical communities.

Clearly, Mr. Feuerstein decided not to include the facts I mention. Right now is a critical time for Provectus and while we, necessarily, needed to postpone an interview with him, we certainly offered to reschedule. **It is my sincere hope that readers will consider what I have outlined and will continue to make their own decisions about our company and its promising drug in development - both now and following our further FDA-guidance-related announcements.**

A copy of this letter is also being filed with the Securities and Exchange Commission as an exhibit to a Current Report on Form 8-K.

Very truly yours,

Peter R. Culpepper, CPA, MBA
CFO, COO
Provectus Biopharmaceuticals, Inc.

81. By the close of trading, Provectus's stock price plummeted $3.35 per share to close at $1.87 per share on January 23, 2014, a decline of nearly 64% on volume of 30.5 million shares.

82. The highlighted statement contained within the January 23, 2014, "Letter to the Editor" was materially false and/or misleading because it: (i) misrepresented the prospects for PV-10 by suggesting an ongoing relationship with the FDA which would lead to future announcements of the FDA's guidance towards a path for PV-10's approval; (ii) omitted reference to the concerns previously communicated by the FDA, as recently as December 16, 2013, "regarding the development program" for PV-10; (iii) omitted reference to the provision of advice by the FDA "regarding the type of data that should be systematically collected to investigate the clinical benefit(s) of an intratumoral treatment of a subset of individual lesions"; (iv) failed to disclose that the Company could not obtain BTD status by implementing the guidance *already provided* by the FDA because Provectus had collected insufficient data during the Phase II trials to demonstrate the secondary endpoints of symptom relief of pain, infection and/or significant bleeding required by the FDA – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*). The statement was materially misleading when made and made with scienter because Defendants attended the Type C meeting with the FDA and knew Provectus could not provide sufficient data on the secondary endpoints of pain, infections and significant bleeding.

83. On January 24, 2014, shortly before noon, Feuerstein published an article on *TheStreet.com* entitled "Provectus Still Won't Answer Key Questions About Skin Cancer Drug PV-l0," which stated, in part:

> Provectus Pharmaceuticals responded to my column about the obsolescence of its skin cancer drug PV -10 with a "letter to the editor" which was also filed as an 8-K.
>
> Read Provectus' letter closely. It's a non-denial denial which fails to address any of the concerns and questions raised in my column. Provectus executives refuse to explain the delay in starting the phase III study of PV-10 metastatic melanoma. As I reported, it's been two years since the company told investors that it had completed meetings with FDA and was ready to seek a Special Protocol Assessment (SPA) for the PV-10 phase III study. If PV-10 is such a promising skin-cancer drug, why has Provectus been unable or unwilling to move the drug into a phase III study, as promised?
>
> Provectus also refuses to explain what made the latest meeting with FDA, held Dec. 18, necessary. The company claims an accelerated approval of PV-10 or Breakthrough Therapy designation is being considered. But on what substantive basis? As I reported, the only clinical study conducted with PV-10 in melanoma was completed four years ago and enrolled 80 patients. Does Provectus really expect FDA to consider this tiny study sufficient for an accelerated approval review? How so? Provectus won't say, which speaks volumes.

84. Needing to get the last word over Feuerstein to try to recover the $3.35 drop in Provectus's share price based upon his withering criticism, twenty minutes later, Provectus bolstered its "Letter to the Editor" issued the day before with a press release entitled "Provectus's PV-10 Path to Initial Approval in U.S. Now Clear Per FDA Meeting Minutes." The next line of the press release trumpeted: "Treatment of 'Locally Advanced Cutaneous Melanoma' to be Path to Initial Licensure." This press release was filed as an exhibit to SEC Form 8-K, also dated January 24, 2014, and signed by Defendant Culpepper. The press release stated in relevant part:

> Provectus Biopharmaceuticals, Inc. (PVCT) (http://www.pvct.com), a development-stage oncology and dermatology biopharmaceutical company, today announced that it has received the official minutes from the Type C meeting held with the FDA's Division of Oncology Products 2 on December 16, 2013. The purpose of the meeting was to determine which of the available paths that Provectus's novel investigational oncology drug PV-10 will take in pursuit of initial FDA approval and commercialization. PV-10, a 10% solution of rose bengal disodium, is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, while inducing a secondary tumor-specific immune response. As a result of this meeting, Provectus will submit data from its

Phase 2 study in a formal breakthrough therapy designation (BTD) request this quarter, and should receive a decision within 60 days of receipt of that request.

With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, the Food and Drug Administration (FDA) was given powerful expedited tools to speed patient access to innovative medicines for serious or life-threatening conditions (Food and Drug Administration Safety and Innovation Act (FDASIA)). **FDASIA initiatives such as breakthrough therapy designation are designed to accelerate approval for new drugs that show preliminary clinical evidence of a large treatment effect**. A key feature of BTD authorizes the Agency to take steps to ensure that the design of the clinical trials are as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment. Requests for BTD are reviewed and granted or rejected within 60 days of receipt. **As Provectus has previously reported, based on rapid tumor destruction in a positive Phase 2 trial in melanoma patients receiving PV-10 (protocol PV-10-MM-02), input from the Agency regarding the current development plan was sought**. Agency guidance (Frequently Asked Questions: Breakthrough Therapies) encourages sponsors to seek such advice prior to formal request for designation.

Chief Executive Officer Craig Dees, Ph.D., observed, "This meeting with the FDA is another significant step forward in streamlining the pathway to initial U.S. approval of PV-10 as the first local agent for recurrent locoregionally advanced melanoma. These patients suffer with troublesome, disfiguring disease that can persist for many years before presenting at distant sites. Our meeting with the Agency established the parameters for submission of a BTD request tailored to addressing the pressing needs of these patients. We're grateful that our work with the Agency, in this and in our previous meetings, to identify a strategy for demonstration of clinical benefit in recurrent patients is bearing fruit. We are very pleased that the path to initial approval in the U.S. is now clear and PV-10 can be available to help patients in a more condensed time frame than if the Agency required an overall survival endpoint in a large randomized Phase 3 study."

The meeting and official meeting minutes provided valuable guidance on a number of issues surrounding the approval path of PV-10:

· The Agency agreed with Provectus that treatment of cutaneous and subcutaneous tumors in patients with locally advanced cutaneous melanoma (i.e., recurrent, in-transit or satellite melanoma that has not yet spread from the skin to distant sites) could provide clinical benefit to such patients, particularly if the measured objective responses in patients' disease correlated to a demonstrated treatment effect on one or more symptoms of their disease (e.g., pain, infection or significant bleeding).

· The Agency agreed to work with Provectus to quantify symptom control in this patient population.

· **In reference to discussions on the potential for breakthrough therapy designation, "FDA advised Provectus to provide objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions**."

The Phase 2 study of PV-10 showed:

· Among all 80 intent-to-treat melanoma patients, 26% achieved a complete response and another 25% achieved a partial response (shrinkage by at least 30%) of their injected study tumors (51% objective response rate, confidence interval 40-63%).

· In the subgroup of melanoma patients that received PV-10 injection into all known disease (28 of the 80 ITT patients), 50% achieved a complete response (71% ORR, CI 51-87%).

· In the subgroup of melanoma patients with locally advanced cutaneous melanoma that received PV-10 injection into all known disease or only had 1 or 2 designated bystander tumors untreated (54 of the 80 ITT patients), a complete response was achieved in 232 of 363 injected tumors (64% of lesions) with the vast majority of these tumors requiring only 1 or 2 injections.

These data show that if a tumor is accessible to PV-10 injection, the drug is likely to destroy that tumor. If approved, PV-10 would be the first tissue-sparing local therapy for recurrent melanoma.

Dees continued, "*The Agency may yet recommend and it may be in the best interest of Provectus to undertake a small, short bridging study in patients where all tumor burden can be injected.* This would allow more frequent dosing than was permitted in the Phase 2 study, presumably akin to the dosing schedule currently used to treat nearly 100 patients under our expanded access protocol, and allow symptomatic endpoints to be prospectively correlated with objective response criteria. Provectus has $18 million in cash reserves and would not require additional capital or the resources of a partner to conduct such a study. If such a study is conducted, it also fits with needs for an international study supportive of licensure in Australia, Europe, China and India."

Dees further stated, "Non-specific local treatments that temporarily reduce tumor burden, such as surgery and radiation, are the most commonly used cancer therapies today. Furthermore, we believe our clinical and immunologic mechanism data show that it may be possible to delay or prevent melanoma metastasis to distant sites."

> Dees continued, "Measurement of tumor shrinkage via objective response criteria has been considered direct clinical benefit in drug approvals for other skin cancers and we believe a similar case can be made for PV-10 in locally advanced cutaneous melanoma. As advised by the Agency, *we will submit data from the 28 patients in our Phase 2 study who had all existing disease treated in a formal BTD request this quarter, and should receive a decision within 60 days of receipt of that request."*
>
> *Dees concluded, "While the rapid ablative effect immediately evident in patients treated with PV-10 highlights our path to initial approval,* the bystander effect continues to be of scientific interest and studies to quantify systemic tumor-specific immune response in cancer patients are ongoing. This emerging understanding of the secondary effect of tumor ablation with PV-10 is an important foundation for future studies to assess the long-term impact of PV-10 on distant metastasis and possible combination strategies for use of PV-10 in the treatment of cancer patients with more advanced disease." (Emphasis added.)

85. The statements highlighted in bold print in the January 24, 2014, press release were materially false and/or misleading because they mislead investors to believe that the minutes indicated that the FDA would accept a BTD application for PV-10 to treat "recurrent locoregionally advanced melanoma" because of "preliminary evidence of a large treatment effect," due to the "rapid tumor destruction in a positive Phase 2 trial" without requiring a Phase III study, thereby advancing commercialization by as much as 2.5 years, upon the provision of "objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions."

86. These statements were made with scienter because Defendants knew that Provectus could not "provide objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions" for the 28 patients referenced from the Phase II PV-10 study because it had not been designed to collect such data – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*).

87. The statements highlighted in italics were materially false and misleading because Defendants led investors to believe that because of the change in focus from metastatic melanoma treatment – intended to show a immunotherapeutic effect by the destruction or shrinkage of non-injected tumors – to recurrent locoregional treatment, all that was needed for approval of Provectus's BTD was a "small, short bridging study" to show tumor ablation in more than the 28 patients who had all their tumors injected with PV-10 in the Phase II study and provision of "objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions."

88. The statements were false when made and made with scienter because once Defendants changed the focus PV-10's indication to a disease that is not immediately life-threatening, they recklessly disregarded that a Phase II study with results from 28 patients was not likely to be a sufficient sample to warrant BTD status without more extensive testing. Moreover, if they were correct that only a "small" study would be required to supplement the results already obtained in the 28 patients, according to the press release, they would have had to also submit "objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding)" for the first 28 patients and knew that they had collected insufficient data during the Phase II trials to demonstrate the secondary endpoints of symptom relief of pain, infection and/or significant bleeding required by the FDA – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*).

89. Even the title of the press release "Provectus's PV-10 Path to Initial Approval in U.S. Now Clear…." was materially false or misleading in that it suggested that PV-10 was on a "clear path" to FDA approval when Defendants, in fact, knew otherwise: Because they had not

gathered the required data during the Phase II trials, Defendants had not addressed, and could not address, the concerns and advice communicated by the FDA regarding PV-10's development program and could not succeed in obtaining BTD status for the newly-chosen, more limited indication of recurrent, locoregionally advanced melanoma that had not yet metastasized.

90. On March 13, 2014, Provectus filed its 2013 10-K. The 2013 10-K was signed by Defendants Dees, Culpepper, and Scott.

91. In the 2013 10-K, the Company again referred to the December 16, 2013, meeting with the FDA and repeated many of the assertions contained in the January 24, 2014, press release and Form 8-K cited above. The 2013 10-K stated, in relevant part:

> A Type C meeting was held with the FDA's Division of Oncology Products 2 on December 16, 2013. **The purpose of the meeting was to determine which of the available paths that our novel investigational oncology drug PV-10 will take in pursuit of initial FDA approval and commercialization.** PV-10, a 10% solution of rose bengal disodium, is designed to selectively target and destroy cancer cells without harming surrounding healthy tissue, while inducing a secondary tumor-specific immune response. As a result of this meeting, we will submit data from its Phase 2 study in a formal breakthrough therapy designation (BTD) request, and should receive a decision within 60 days of receipt of that request.
>
> With the passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in July 2012, the Food and Drug Administration (FDA) was given powerful expedited tools to **speed patient access to innovative medicines for serious or life threatening conditions.** FDASIA initiatives such as breakthrough therapy designation are designed to **accelerate approval** for new drugs that show preliminary clinical evidence of a large treatment effect. A key feature of BTD authorizes the FDA to take steps to ensure that the design of the clinical trials are as efficient as practicable, when scientifically appropriate, such as by minimizing the number of patients exposed to a potentially less efficacious treatment. Requests for BTD are reviewed and granted or rejected within 60 days of receipt. As we have previously reported, based on rapid tumor destruction in a positive Phase 2 trial in melanoma patients receiving PV-10 (protocol PV-10-MM-02), we sought input from the FDA regarding our current development plan. FDA guidance encourages sponsors to seek such advice prior to formal request for designation.
>
> **We believe that this meeting with the FDA is another significant step forward in streamlining the pathway to initial U.S. approval of PV-10** as the first local

agent for recurrent locoregionally advanced melanoma. These patients suffer with troublesome, disfiguring disease that can persist for many years before presenting at distant sites. **Our meeting with the FDA established the parameters for submission of a BTD request tailored to addressing the pressing needs of these patients**. The meeting and official meeting minutes provided valuable guidance on a number of issues surrounding the approval path of PV-10:

> • The FDA agreed with us that treatment of cutaneous and subcutaneous tumors in patients with locally advanced cutaneous melanoma (i.e., recurrent, in-transit or satellite melanoma that has not yet spread from the skin to distant sites) could provide clinical benefit to such patients, particularly if the measured objective responses in patients' disease correlated to a demonstrated treatment effect on one or more symptoms of their disease (e.g., pain, infection or significant bleeding).
>
> • The FDA agreed to work with us to quantify symptom control in this patient population.
>
> • In reference to discussions on the potential for breakthrough therapy designation, "**FDA advised Provectus to provide objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions.**" (Emphasis added.)

92. The quoted statements from the 2013 10-K (particularly the ones highlighted in bold) were materially false and/or misleading because they: (i) misrepresented the prospects for PV-10; (ii) failed to disclose that the Company could not follow the "parameters" established by the FDA for submission of the BTD application for PV-10; and (iii) failed to disclose that because the Phase II study had not been designed to collect, and thus failed to generate, secondary endpoint data – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*) – Provectus could not "provide [the FDA with] objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions."

93. On March 24, 2014, Provectus issued a press release entitled "Provectus Biopharmaceuticals Inc. Submits Application to FDA to Receive Breakthrough Therapy

Designation for PV-10 for Treatment of Melanoma - FDA Expected to Make Determination Within 60 Days upon Receipt." This press release was attached as an exhibit to SEC Form 8-K, dated March 24, 2014, and signed by Defendant Culpepper. The press release stated in part:

> Provectus Biopharmaceuticals, Inc., a development-stage oncology and dermatology biopharmaceutical company, announced today that it has applied to the FDA for Breakthrough Therapy Designation (BTD) for PV-10 for the treatment of melanoma. FDA guidelines state that the Agency will make a decision on the application within 60 days of receipt. The Agency's records for FY 2013 show that the Agency's Center for Drug Evaluation and Research (CDER) met that guideline 97% of the time.
>
> Craig Dees, PhD, CEO of Provectus said, "The decision to apply for BTD stems from our Type C meeting held with the FDA's Division of Oncology Products 2 in December 2013. At the meeting FDA expressed willingness to work with Provectus toward initial approval for the novel investigational oncology drug PV -10 in locally advanced cutaneous melanoma. This included a statement in the minutes that data in a cohort of patients that received PV -10 to all existing lesions should be submitted in a formal BTD application."
>
> Dees continued, "I want to make clear to our shareholders, the media and the market as a whole that BTD is not guaranteed and if the designation is conferred on PV-10 for melanoma, it does not bypass the need for a new drug application (NDA) and review, as both are required for commercialization of any drug. **As I have stated previously, the Agency may yet recommend and it may be in the best interest of Provectus to undertake a small, short bridging study in patients where all tumor burden can be injected. This could occur either before or after we have approval to sell PV-10**. Provectus has over $16 million in cash reserves and would not require additional capital or the resources of a partner to conduct such a study. If such a study is conducted, it also fits with needs for an international study supportive of licensure in Australia, Europe, China and India."
>
> Dees concluded, "**We are confident that the studies done thus far illustrate the effectiveness and safety of PV-10: if you inject PV-10 into melanoma tumors, the tumors go away.** For recurrent, aggressive skin cancers this unique mechanism confers tangible benefit to patients." (Emphasis added.)

94. The March 24, 2014, press release was materially false and/or misleading because it: (i) misrepresented the prospects for PV-10; (ii) failed to disclose that the BTD application could not and did not contain the required data established by the FDA for submission of the BTD application for PV-10; and (iii) failed to disclose that because the Phase II study had not

been designed to collect, and thus failed to generate, secondary endpoint data – a fact later admitted by Defendant Wachter (*see* ¶111, *infra*) – Provectus could not "provide [the FDA with] objective response rates with adequate information to evaluate the symptomatic treatment effects (e.g. pain, infection, bleeding) in patients presenting with locally advanced cutaneous melanoma who received PV-10 to all lesions."

95. The press release was further false and/or misleading in that it misrepresented, for the first time, that Provectus could conduct a so-called "bridging study" *after* the FDA granted approval to market and sell PV-10 to the public. While it may be true that a pharmaceutical company might want to conduct a bridging study to show bioequivalence for an FDA-approved drug to be sold sell internationally[4] (as discussed in Provectus's January 24, 2014, press release), the type of "bridging study" earlier mentioned did not appear to be one that could be conducted after FDA approval. In particular, Defendants' description of the study, to "allow more frequent dosing than was permitted in the Phase 2 study, presumably akin to the dosing schedule currently used to treat nearly 100 patients under our expanded access protocol, and allow symptomatic endpoints to be prospectively correlated with objective response criteria," appears to be an expanded Phase II study to treat the full tumor burden of more than just 28 patients and collect the secondary endpoint data required. This statement was materially false and/or misleading when made, and Defendants knew that to be so, because Defendants knew that the FDA would not allow Provectus to market and sell PV-10 based upon a 28-patient sub-sample of the earlier Phase II trials and would require sufficient testing with objective response criteria *before* granting approval.

[4] *See*, *e.g.*, International Conference on Harmonisation; Guidance on Ethnic Factors in the Acceptability of Foreign Clinical Data; Availability, 63 Fed. Reg. 31790, 31792 (June 10, 1998).

96. On May 8, 2014, Provectus filed its SEC Form 10-Q for the quarter ended March 31, 2014 (the 1Q14 10-Q). The 1Q14 10-Q was signed by Defendant Culpepper, and certified by Defendants Dees and Culpepper.

97. The 1Q14 10-Q stated, in part:

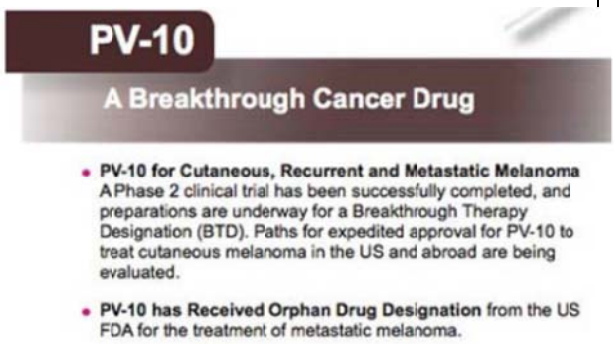
> As reported previously, a Type C meeting was held with the FDA's Division of Oncology Products 2 on December 16, 2013. **The purpose of the meeting was to determine which of the available paths that our investigational oncology drug PV-10 could take in pursuit of initial FDA approval and commercialization**. As a result of this meeting, we submitted data from our Phase 2 study in a formal BTD request on March 21, 2014.
>
> A breakthrough therapy is defined as a drug that is intended, alone or in combination with one or more other drugs, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For drugs and biologics that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. **Drugs designated as breakthrough therapies by the FDA are also eligible for accelerated approval.** (Emphasis added.)

98. The 1Q14 10-Q disclosed, however, whereas the 2013 10-K did not, that "***A breakthrough therapy designation (BTD) by the FDA for our product candidate may not be granted or lead to a faster development or regulatory review or approval process, and it does not increase the likelihood that our product candidate will receive marketing approval***." (Emphasis in original.) Because Defendants knew that the BTD application did not contain the required secondary endpoint objective response data, they made this statement to soften the blow to investors when the application was denied later that month. Specifically, having touted BTD status as a path to commercialization with a more "condensed time frame than if the Agency required … a large randomized Phase 3 study," Defendants *now* downplayed the time savings of BTD status.

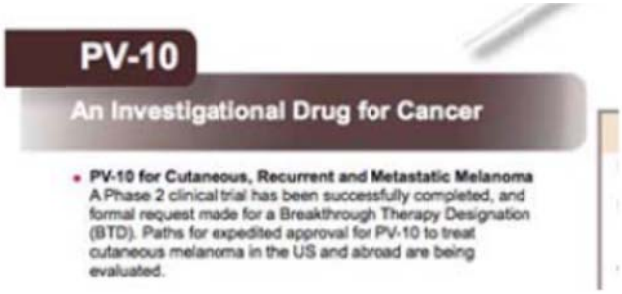
99. On May 20, 2014, Feuerstein noted in an article published on *TheStreet.com* that Provectus had described its PV-10 drug as a "breakthrough" drug for skin cancer on its website prior to the FDA designating the drug as such. The drug was described as "breakthrough" on the Company's website up until May 19, 2014. On or about May 20, 2014, the description of the drug on the website was amended to "investigational."

100. According to Feuerstein's May 20, 2014, article on *TheStreet.com*, the below images were screenshots taken of Provectus's website on May 19, 2014, and May 20, 2014.

May 19, 2014:



May 20, 2014:



101. The term "breakthrough" as applied to drugs and treatment therapies in the pharmaceutical and medical industries is a term of art with a specific meaning that indicates that the drug/therapy will undergo an accelerated and expedited FDA review and approval process. Defendants' description of PV-10 as a "Breakthrough" cancer drug on Provectus's website prior to the FDA's designation of the drug as such was materially false and/or misleading to Provectus investors. This is especially true because even the "fine print" is misleading: the initial description suggests that Provectus is getting prepared for a BTD that will certainly occur ("preparations are underway for a Breakthrough Therapy Designation"), while the revised language is neutral ("formal request made for Breakthrough Therapy Designation"). Interestingly, although Defendants later claimed to have only received notice of the BTD denial

on May 21, 2014, the date of the FDA's letter was May 16, 2014, and the change occurred between the two dates.

102. Subsequently, on May 21, 2014, a blogger on *SeekingAlpha.com* highlighted the continued failure of Provectus to commence a Phase III trial of PV-10, and alleged that the Company was tied to a stock promotion firm whose reports had recommended stocks in which trading had been recently halted by the SEC. The article titled "Provectus: Strong Sell, Ties To Paid Stock Promoters, SEC Halt Risk, Price Target $0," stated in part:

> • PVCT has just FOUR full-time employees, HQ appears to be a metal barn in rural Knoxville, claim to have effective treatment for cancer with commodity red dye "Rose Bengal."
>
> • PVCT is connected to questionable paid stock promoters whose other recommendations have recently been halted by the SEC: including FSPM, PHOT, and PTOG.
>
> • Insiders were paid -$49m during a 12+ year period while PVCT shareholders accumulated losses -$150m with zero revenue and shares outstanding have increased 20x.
>
> • PV-10 has no Phase 3 trial in sight while patents begin expiring in 2016 and appears to have failed their FDA Breakthrough Designation Request.
>
> * * *
>
> *My research has discovered numerous issues with PVCT including:*
>
> 1. PVCT is connected to questionable stock pumpers promoting PVCT including Small-Cap Street LLC. Multiple stocks covered by Small Cap Street LLC have recently been halted by the SEC and I believe PVCT could be next to be halted given its weak disclosures and zero revenue.
>
> 2. PVCT's PV -10 researcher Dr. Sanjiv Agarwala has a history of failure and has been sued by the SEC for insider trading. Dr. Sanjiv also recently presided over the famous VICL trial failure, resulting in VICL stock price implosion and drug abandonment.
>
> 3. PVCT board and management are associated with multiple, very questionable paid stock promotions and companies that wiped out shareholders.
>
> 4. The founders of PVCT's last company, Imcor Pharmaceutical Company which had the PH-l0 drug, stock was also a complete shareholder wipeout.

> 5. PVCT management received stated compensation of $49m since inception while paying over ten million dollars to unnamed "consultants" - all while the company has lost -$150m and never generated material revenue over the past 12 years.
>
> * * *
>
> 7. PVCT's claims of PV-10 are incredulous and the lack of a credible large pharma partner taking a stake in the company or Phase 3 trials strongly indicate the drug is unviable.
>
> 1. If PV-10 was so groundbreaking, why is PVCT the subject of a paid promotion campaign with questionable stock promotion outfits?
>
> 8. Recent PVCT website changes strongly indicate to me the BTD application was not approved.
>
> * * *
>
> PVCT is a reverse merger stock which uplisted this week to the NYSE with an incredible -$750m market cap after running up over 300% from 80 cents/share under 6 months ago. How did PVCT, a company with $0 revenue and little cash, accomplish this? I believe much of the current demand for PVCT stock is connected to questionable stock promoters potentially aimed at unsophisticated retail investors. When that promotion runs out of steam, I believe PVCT stock price will likely implode as PVCT already has achieved one of the highest market capitalizations I have ever seen for a company of this nature.
>
> In January "Small-Cap Street" issued a report claiming PVCT is worth $62 per share written by "Osman Ghani" whose resume lists no biotech or pharma experience. Osman Ghani has recently authored numerous reports on a variety of stocks as a paid article writer, including NVLX, another penny stock paid promotion. Osman Ghani also recently wrote about PTOG, recently halted by the SEC. In fact, two other stocks covered by Paul Lipp's firms were also halted by the SEC recently (more below).

103. On May 21, 2014, before the market closed, Provectus (as it had done so adamantly in the past with respect to Feuerstein's articles on *TheStreet.com*) issued a press release directly refuting supposed inaccuracies in *SeekingAlpha.com* blog article. This press release was filed as an attachment to SEC Form 8-K, also dated May 21, 2014, and signed by Defendant Culpepper. The release stated, in part:

> It has come to the attention of Provectus Biopharmaceuticals, Inc., a development-stage oncology and dermatology biopharmaceutical company (the "Company" or "Provectus"), that an article was published on seekingalpha.com on May 21, 2014, which contains numerous inaccuracies and misstatements about

the Company. Without attempting to address every false statement and inaccuracy contained in the article, the Company wishes to address some of the misinformation with the following facts:

• The article alleges that the Company's oncology drug PV -10 "appears to have failed their Breakthrough Therapy Designation." This statement is completely false. **The FDA has not reported back to the Company with respect to the Company's application for Breakthrough Therapy Designation**.

• The article indicates that Provectus is "connected to questionable stock pumpers promoting PVCT including Small-Cap Street LLC." To the contrary, Provectus is not connected in any way to Small-Cap Street LLC or any other similar promoter.

• The article indicates that Provectus's patents begin expiring in 2016. In actuality, the most important patent with respect to PV-10 does not expire until 2031, and of the eight patents that expire in 2016, none of the patents relate to PV -10; seven of the patents relate to medical devices and one relates to dermatology.

• The article's summary concludes by saying "PVCT appears extraordinarily overvalued with -$750 MILLION fully diluted valuation. I believe fair value is closer to $0 and outline why in this report." Because the article is based on numerous inaccuracies, this "belief" is unfounded.

The legitimacy of any article authored by a pseudonym has to be questioned. The Company is at a loss as to why individuals would be attempting to disparage the Company, but the Company will continue to proceed with our business and plans as we have in the past. (Emphasis added.)

104. On this news, Provectus's stock price dropped $0.22 per share to close at $2.02 per share on May 22, 2014, a one-day decline of nearly 10%, on heavy volume. Again, the losses likely would have been even higher but for Defendants' continued false and/or misleading statements attempting to counter the *Seekingalpha.com* article.

VIII. ANNOUNCEMENT OF THE FDA'S DENIAL OF BREAKTHROUGH THERAPY DESIGNATION FOR PV-10

105. The FDA issued a letter denying the application for BTD for PV-10 on May 16, 2014. Defendants, however, did not disclose the receipt of the FDA's May 16, 2014, denial of BTD status for PV-10 until May 23, 2014. (Defendants later admitted that Provectus received a notice from the FDA on May 21, 2014.) During the week between the notice of denial being

sent and Defendants' disclosure of that fact Defendants mysteriously corrected Provectus's website (on or about May 20, 2014) and Defendants stated, in a press release filed with the SEC at 3:32 pm on May 21, 2014, that the FDA had "*not reported back to the Company*" concerning the BTD application, although a blogger claimed earlier that day that Defendants' changes to the website indicated that it had been denied.

106. On May 23, 2014, Provectus filed a SEC Form 8-K, signed by Defendant Culpepper, disclosing the Company's receipt on May 21, 2014, of the FDA denial notice dated May 16, 2014. The May 16, 2014, FDA notice of denial letter stated, in part:

> Dear Dr. Wachter:
>
> Please refer to your Investigational New Drug Application (IND) submitted under section 505(i) of the Federal Food, Drug, and Cosmetic Act for "PV-10 (rose bengal disodium in 0.9% saline)."
>
> We also refer to your March 21, 2014, request for Breakthrough Therapy designation for treatment of locally advanced cutaneous melanoma. Furthermore, we refer to our comments and information requests made via email communication on April 11, 2014, and to your amendment dated April 14, 2014, containing your responses to the April 11, 2014 communication.
>
> We have reviewed your request and while we have determined that treatment of "locally advanced cutaneous melanoma" meets the criteria for a serious or life-threatening disease or condition, **the preliminary clinical evidence you submitted does not indicate that the drug may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints**. Therefore, designation as a Breakthrough Therapy cannot be granted at this time.
>
> The preliminary clinical data provided in your request for Breakthrough Therapy designation are indicative of drug activity in the treatment of local, satellite or in-transit recurrence of malignant melanoma; however, **the preliminary clinical data do not demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints. This determination is based on the paucity of data on endpoints indicative of clinical benefit (e.g., pain, infection, significant bleeding) and our inability to determine the clinical significance of the reduction in the size in one to 10 target lesions in patients with locally advanced melanoma**, who may have additional untreated cutaneous, subcutaneous, or visceral sites of disease. The information provided on durability of response is also of unclear clinical significance given the modifications to

> RECIST. Finally, there was also **insufficient information provided in the package to ascertain improvement in or relief of tumor-related symptoms of pain, bleeding, or tumor ulceration**. We acknowledge that a subset of patients with pre-treatment pain was identified, with summary data presented for two post-treatment time-points (at 8 and 13 weeks). However, from the information provided using visual analogue scale (VAS) for assessment of pain is incomplete as it did not capture pain throughout the course of treatment, no information on concomitant pain medications were provided, and it is not clear that the results observed were clinically significant, as no information was provided on validation of the VAS instrument used.
>
> **FDA previously communicated concerns regarding the development program and provided advice regarding the type of data that should be systematically collected to investigate the clinical benefit(s) of an intratumoral treatment of a subset of individual lesions in a systemic disease (malignant melanoma), as previously discussed at the April 8, 2010, March 7, 2011, and October 18, 2011, end-of-Phase 2 meetings and the December 16, 2013 General Guidance teleconference.** Please note that your request for Breakthrough Therapy designation was discussed with representatives from the Center for Drug Evaluation and Research (CDER) and from the Office of New Drugs (OND) and Office of Medical Policy (OMP) within CDER, who concurred with the Division's assessment.
>
> You may submit a new request if you obtain new clinical evidence that PV-10 demonstrates a substantial improvement over existing therapies on one or more clinically significant endpoints in the treatment of locally advanced cutaneous melanoma. (Emphasis added.)

107. Immediately following the Company's announcement of the FDA denial of BTD for PV-10, Provectus held a conference call at 4:00 P.M. EDT on May 23, 2014. Defendants Culpepper and Wachter participated in the call. Defendant Dees was conspicuously absent from the call.

108. During the call, Defendant Wachter attempted to assuage investor concerns by downplaying the significance of the FDA's denial of BTD for PV-10, yet he conceded that BTD status would have conveyed Provectus certain advantages in the market:

> …the Agency has refused to grant BTD applications in nearly two-thirds of the cases since it adopted this as a method to moving drugs along more quickly in 2012.

> Failure to receive BTD does not mean the end of the road for a drug. And we need to stress that. The FDA has not said PV-10 is a dead end. In fact, it's reinforced the relevance of it, uh, potentially for patients.
>
> When we announced, uh, our application for BTD back in March of 2014, we stated in the press release that BTD is not guaranteed. And if a designation is conferred on PV-10 for melanoma, it does not bypass the need for a new drug application or NDA and review of that NDA, as both are required for commercializing any drug.
>
> Historically, **BTD has conferred some advantage in terms of time of market**. But it still takes an average of 10 months from receiving the designation to, uh, commencement of sale of the product.

109. Defendant Wachter also repeated the Company's unexplained statement that FDA approval to publicly sell PV-10 to the market may come *before* the Company had completed testing. Wachter stated that the FDA "may yet recommend, and it may be in the best interest of Provectus, to undertake a small, short bridging study in patients where all tumor burden can be injected. This could occur either before or after we have approval to sell PV-10."

110. Again, while a bioequivalence bridging study might be appropriate *after* FDA-approval to the extent Provectus sought to sell PV-10 in a different region of the world, the study described seemed to be a more robust Phase II study providing the exact same treatment – injection of all tumors – only provided to 28 patients in the earlier Phase II study. Defendants failed to explain how the study they described was a bridging study or how PV-10 could be sold prior to the completion of that study and the FDA approval process.

111. Defendants also addressed the December 16, 2013, meeting with the FDA regarding PV-10. Referring to "lengthy discussions" with the FDA, Defendant Wachter shockingly admitted that Defendants knew at the time that the Company's Phase II study of PV-10 was not designed to include the information that the FDA told Defendants in December 2013 it would need in order to approve PV-10, stating:

> …we had **lengthy discussions with the Agency in our December 2013 meeting**, uh, on the outcome in these patients, discussed the, uh, the objective response parameters that I've just outlined.
>
> And **the Agency asked us for, uh, additional evidence showing that those responses correlated with, uh, symptomatic improvement in the patients**. That is, improvement in things such as pain, lesions, bleeding in the lesions, infection in the lesions, and so on.
>
> Uh, unfortunately, the phase two study did not require patients to have baseline symptoms in these types outside, uh, the existence of biopsy proven melanoma for enrollment.
>
> And **we did not design the study to collect the type of detailed information on symptoms that might be ideal for showing that correlation**. (Emphasis added.)

112. In response to a question whether the study would be re-designed moving forward such that the Company would be sure to collect data on the relevant end points required by the FDA, Defendant Wachter suggested that, even prior to the Company's receipt of the FDA notice denying BTD for PV-10, the Company already had started the process of re-designing the PV-10 study:

> We have, obviously, uh, spent some amount of effort discussing with our, uh, advisors, uh, what sort of measurements we might make to, uh, capture, uh, symptomatic improvement.
>
> And we also went to an FDA workshop two weeks ago in Washington, uh, that principally was related to the design and use of, uh, tools to measure patient reported outcomes.

113. Defendants Culpepper and Wachter tried to save face by reassuring investors of PV-10's critical importance to saving lives, as well as its path to FDA approval:

> **Culpepper**: Well, the reason we'll be successful, Albert, is because we do have a drug that works, as Eric indicated.
>
> **Mr. Albert Gueedo**: Okay.
>
> **Culpepper**: It works very well. . . . [T]he active pharmaceutical ingredient, of course, has been preapproved by the FDA, as we know on this call, has been a preapproved, uh, agent.
>
> **Wachter**: Previously approved.

Culpepper: Previously approved in, uh two different diagnostic applications. It's a well-known compound. We're the only ones using it therapeutically. Uh, and so, we have a very rare opportunity to take a very effective, very well-tolerated agent.

It's just unusual, because . . . [i]t's delivered, of course, locally, intralesionionally. And this is where the importance we should emphasize, the importance of the data at ASCO June 2nd.

It's very . . . critical to help the oncology community better understand the way PV-10 is working in a unique fashion. So, that's how we're going to deal with people.

Mr. Albert Gueedo: But we're saving lives here. We're saving lives.

Culpepper: Exactly. Exactly.

Mr. Albert Gueedo: And this nonsense, this--I say it's a political ploy with the FDA and so on. We have it in black and white. What more do they want? It's ridiculous.

Wachter: So, it's really come down to, Albert, it's data in a certain fashion for the Agency to understand, to support the approval of the drug. The data has to be in such a way that the regulators can assimilate.

And that's, you know--and we--this is what we will ensure that we will continue to work on because we know it's saving lives. We know the patients that we have treated successfully, that have no evidence of disease years after.

So, yes, this is absolutely critical we continue to proceed. And we have no question in our minds that we will, uh, continue and be successful simply because the drug works.

114. Knowing how surprised and disappointed investors would be, Defendants sought to be prepared to explain what happened by "draft[ing] some anticipated questions in advance of the call today." Defendant Wachter read from one pre-drafted (by Defendants) question that was captioned, "Aren't You Mad as Hell at the FDA?" In response to this self-posed question (and suggestion of blame directed by Defendants to the FDA), the Company stated, in part:

[W]ithin the denial letter, there are some very positive statements. For example, it's very significant the Agency has clearly stated that the data presented indicates that PV-10 is active in melanoma.

And furthermore, they recognize that the condition that we identified as the lead indication, locally advanced cutaneous melanoma, meets the criteria for a serious

or life-threatening disease or condition. These are dramatic changes in position from the Agency, uh, versus where we stood two years ago, when we had, uh, a third type B meeting with the Agency.

…[N]onetheless, at the end of day, we must work within the existing regulatory framework for the benefit of the patients. And the Agency's letter provides valuable insight into what additional data is needed to demonstrate clinical benefits.

115. In response to an investor question regarding the requirements that the FDA communicated to Defendants regarding seeking BTD for PV-10, Defendants again indicated that they knew *much earlier* than May 2014 that the Company's PV-10 study was not designed to adequately capture the information requested by the FDA in order to qualify for BTD status. In fact, Defendants knew as of the December 2013 meeting with the FDA that obtaining BTD for PV-10 was not likely based on the available study:

Mr. Joseph Baffo: Hi, Pete and Eric.

…Eric, after listening to your comments, it sounds to me when the FDA--I believe the quote was attributed to the, um, in Jan 24th release was that the FDA agrees with Provectus that the destruction of the primary tumor is clinically beneficial and relevant.

And that's why you guys were so excited because of the 64 percent complete response rate. **But what you then had to do was go back a trial from three years earlier and basically go back at a trial that wasn't run for bleeding, and pain, and all the things that they wanted to see in order to say, "Here's how you get your Breakthrough Designation."**

…I don't want to put words for you, but was the reason why you guys were so excited about the opportunity for Breakthrough because you had such a great response rate, 64 percent complete, uh, response, and all the burden was hit.

Uh**, is that[] where it went wrong? That we went back to a trial, and they were asking you guys to give them stuff that was inefficient because that was what the trial was never meant for?**

Wachter: **Yes, to make a very short answer**.

So, the longer version of my answer is that, uh, definitely we were very encouraged by the, uh, guidance that we received from the Agency in that meeting. Uh, that being said, uh, I described myself recently as being a professional worrier.

…[M]aybe that's good for someone who is responsible for clinical development in a small company. **But, uh, I was worried about being able to conclusively demonstrate a correlation between, uh, this high level of objective response**, and I'll use that loosely. What I mean by that is objectively observable response, uh, evidenced by complete responses in patients.

So, all of their disease is gone after PV-10 injections in 50 percent of those patients, uh, versus what I knew was very thin data concerning the types of symptoms that the Agency was suggesting should be shown, uh, improvement in.

And so, we did our best with that study. [L]ooked at, as I mentioned earlier, pain data, and we were able to draw some, uh, supporting evidence to show that there is definitely a trend in pain data that matches the trend in objectively observed response of tumors.

…**[T]he Quality of Life EORTC-QL2-C30 instrument, this . . . 30-question questionnaire**, uh, that's principally designed for patients with, uh, late stage systemic disease, uh, maybe that are taking toxic chemotherapy, **I had great concerns that that was not going to be valuable because we had already shown in the full analysis for [unintelligible] patients in studies that there were no clear trends . . . evident other that the patients . . . didn't get worse . . . and that proved to be correct**.

There was nothing that we could extract from that particular instrument. So, it was a measured risk, uh, submitting the application. But again as I mentioned earlier, uh, our logic seemed clearer that if we were making the patients' tumors disappear in 50 percent of the patients that was a very large effect size, and that was tantamount to making any symptoms that they might have been suffering from the tumor burden, uh, disappear. (Emphasis added.)

116. When pressed by a shareholder during the May 23, 2014, conference call why it appeared that Defendants failed to follow the guidance given earlier by the FDA regarding steps to approval, Defendant Wachter was extremely evasive:

Operator: One next question comes from . . . a private investor. Please proceed with your question.

[private investor]: Thank you, operator.

And, uh, thank you for the opportunity, guys. Um, as a late investor who's been doing this for more than five years, just a couple of questions, firstly, um, Eric, I think it's great that you're on a call. And I think you should do that on a fairly regular basis, if I may suggest.

> The first question, I read the FDA letter a number of times. And I get the sense that we're like the star pupil in the class. And the teacher says you gotta do the exam this way to pass. And we're not listening.
>
> The paragraph on page two says kind of we told you guys on four occasions, and they give us the dates, of the kind of data we need. It just feels, and maybe I'm a layperson here, Eric. So, forgive my ignorance.
>
> It kind of feels they keep telling us to do it in this way. And we feel as though we're smarter and not listening, saying, no, we can do it another way. Is that misplaced, that observation or without foundation?
>
> **Wachter**: Um, I can understand that as an interpretation of the situation. Um, what I'd like to do is turn to, uh, another one of these talking points. I'm sorry.
>
> **[private investor]**: No, of course. Sure.
>
> **Wachter**: It's easier for me to get all of the items right. And it's a long, complicated story. Um, and this particular talking point is captioned. And I came up with this one. Why did it take four years from the end of phase two--end of the phase two study to arrive at this point?

117. Defendant Wachter actually went on to admit that the FDA expressed doubt to the Company in April 2010 as to the viability of PV-10 receiving approval for melanoma treatment, because the FDA doubted the effectiveness of PV-10 to treat melanoma, because the FDA challenged the Company's PV-10 study (in terms of its patient population and end points), and because at least two other drugs, whose efficacy already had been established, already were on the verge of receiving FDA approval for melanoma treatment:

> …in April of 2010, the melanoma landscape was beginning to change very rapidly with ipilimumab and vemurafenib approvals approaching on the horizon.
>
> …[T]his meeting . . . established that what we proposed at the time for phase three study in patients . . . with a patient population and end point similar to studies underway at that time under special protocol assessment for two other investigational intralesional therapies for melanoma . . . would not be appropriate going forward.
>
> So**, the Agency told us . . . that they did not like our proposed patient population . . . nor our end points, and . . . also cast tremendous amount of doubt on the relevance of the drug in melanoma, a disease that . . . they noted was . . . systemically malignant and . . . would be difficult to treat with a local therapy**. (Emphasis added.)

118. Although Defendants did not publicly disclose that they decided to only seek approval for recurrent locoregional tumors until January 2014, Defendant Wachter further admitted that the FDA reiterated its concern as to the efficacy of PV-10 (a local treatment therapy) to treat metastatic melanoma (a systemic disease), as well as concern with the Company's proposed studies, in October 2011:

> **The Agency [in October 2011] expressed continued concern** about enrolling patients with any history of visceral disease based on the concern I mentioned earlier, **that there was inadequate support for use of PV-10 intralesionally in patients with systemic disease, so local therapy for patients with systemic disease.**
>
> …[T]hey also expressed concern about our proposed effect size . . . which we were willing to address. At the conclusion of the meeting, we agreed to develop a revised RCT design in patients with no history of visceral disease and no active nodal disease, um, and to submit this for SPA.
>
> Now in light of . . . our discussions in the second and third meetings with a lead medical reviewer concerning adequacy of support for potential distant effects of PV-10 ablation . . . which we had noticed in our so-called bystander effect in cutaneous lesions, untreated cutaneous lesions in phase one and in phase two testing, and in . . . a limited number of patients with . . . visceral mets at enrollment in the phase two study.
>
> …[S]ome of them showed . . . regression of their untreated visceral mets over the study interval in a fashion similar to . . . some other drugs that were being developed for melanoma at the time.
>
> …[W]e realized we needed to get the story straight on this systemic effect . . . before we could have significant traction with regulators in the U.S. and presumably abroad.
>
> And so, we began a dialogue with researchers from Moffit Cancer Center early the following--I'm sorry--actually we began . . . that dialogue early in 2011. So, between the . . . the second and third [FDA] meeting . . . that by the end of that year evolved into formal nonclinical studies on the cellular basis underlying the bystander effect.
>
> And eventually, it matured into the translational medicine study . . . that's began in early 2013 that we are expected to hear results on . . . June 2nd at ASCO. (Emphasis added.)

119. Finally, addressing the December 16, 2013, meeting with the FDA, Defendant Wachter stated:

> At that meeting, we provided an overview of PV-10 data in melanoma from both phase one and phase two melanoma studies from our expanded access protocol, which now has, uh, enrolled over 100 patients, uh, from our hepatic tumor study, from an investigator-initiated study of PV-10, followed by radiation therapy for treatment of melanoma, and from the afore-mentioned Moffit study.
>
> This data included an exploratory subgroup analysis presented earlier that year at the European Cancer Conference and included response metrics for patients having all or substantially all other baseline disease [unintelligible] with PV-10.
>
> **We also presented a straw man outline for Breakthrough Therapy Designation request and asked for advice on such requests**. To our surprise, in the meeting the Agency focused on the echo, uh, 2013 subgroup analyses and clinical response evidenced in these patients via clinical photography.
>
> **We had a lengthy discussion, uh, regarding patients with locally advanced cutaneous melanoma, the need for therapies for these patients, and the types of end points appropriate for demonstration of clinical benefit**.
>
> Based on our positive impression and discussions from the meeting in the Breakthrough--I'm sorry--in the meeting minutes released a month later, we prepared and submitted our Breakthrough Designation application in March.
>
> So, I warned you there was, uh, a long road, a difficult, complicated story. Um, and what it shows is that as **our understanding of PV-10 has matured over time and as the, uh, melanoma landscape has evolved over time, our interaction with the Agency has improved over time in that we now are in a position that the Agency has helped us to define indications that they believe our drug shows potential value and have helped us to define types of end points that are vastly different than perhaps progression-free survival in the proposed, uh, phase three randomized control trial from the third type C meeting**, uh, which would have used, uh, DTSC [sp?] as a comparator.
>
> Um, it's impossible to run that study, uh, the current climate. We wouldn't enroll patients with the appropriate, uh, extent of disease burden. Uh, so, yes, uh, I can understand the feeling that maybe we're the, uh, the clever student in class that doesn't listen to the advice of the teacher.
>
> Um, but I would prefer to think that we've been working with the Agency to understand, uh, what proved to be a very difficult challenge. We're taking a new class of agent. And there's superficial similarities to other investigational drugs currently under phase three investigation or recently under phase three investigation.

> But those similarities are superficial at best. Uh, the effect of the drug immediately via its primary ablation is very different than other drugs that have been developed.
>
> Uh, the secondary immunologic response that appears to occur in a large fraction of patients, as evidenced by the data coming out of Moffit, is very different than what has been shown in the past.
>
> Um, and understanding what patients might benefit, uh, in a clinical trial setting, uh, has been complicated. **I think we have very good guidance now from the agency in terms of, uh, types of patients to look at, uh, types of end points to use**.
>
> And, uh, **I hope that we'll be able to convince, uh, all people that are watching this story that we're definitely listening to the teacher**. (Emphasis added.)

120. When asked about support for the Company and PV-10 from doctors and other medical professionals in the oncology community, Defendant Wachter stated:

> [W]e have very aggressively increased our involvement . . . with key opinion leaders in the medical oncology community, um, in the--over the past year.
>
> …**[N]ow that we have an immunologic story, it shows that there is . . . potentially a systemic benefit . . . for this crazy--I mean it sounds crazy. This crazy drug that you inject into a tumor might make, uh--in your skin might make a tumor in your lung go away.**
>
> …**[W]e now have an immunologic basis to say that that's quite possible**.
>
> * * *
>
> **That's . . . attracted the attention of that community, which has been, uh, less than responsive to us**. (Emphasis added.)

121. Before trading began on May 23, 2014, trading in Provectus stock was halted at $2.02 per share, "pending news." After the bad news investors received, initially with the press release announcing the denial of the BTD application and, later, when Defendants admitted for the first time that they had knowingly and arrogantly failed to provide the information the FDA requested, thereby dooming the submission, the market's reaction was understandably harsh. When trading resumed on May 27, 2014, Provectus closed at a mere $0.75 on extremely heavy trading. Given the large number of outstanding shares (more than 172 million as of March 7,

2014), Defendants were responsible for causing very substantial damage to Plaintiff and the Class.

IX. LOSS CAUSATION

122. During the Class Period, defendants materially misled the investing public, thereby inflating the price of the Company's securities, by publicly issuing false and/or misleading statements and/or omitting to disclose material facts necessary to make Defendants' statements, as set forth herein above, not false and/or misleading. Said statements and omissions were materially false and/or misleading in that they failed to disclose material adverse information and/or misrepresented the truth about the Company's operations, manner of doing business, and prospects as alleged herein. These material misstatements and/or omissions had the cause and effect of creating in the market an unrealistically positive assessment of the Company, thus causing the Company's common stock to be overvalued and artificially inflated at all relevant times.

123. Lead Plaintiff and the class were damaged when the price of the Company's shares significantly declined when the materially misleading statements and misrepresentations made to the market, and/or the information alleged herein to have been concealed from the market, and/or the effects thereof, began to be revealed, causing investors' losses.

124. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the economic loss suffered by Plaintiff and the Class.

125. After the revelations alleged above were absorbed by the market, the Company's stock was hammered by massive sales, sending the stock's price down from its Class Period high of $6.03. As a result of their purchases of Provectus common stock during the Class Period, plaintiff and other members of the Class suffered economic loss, *i.e.*, damages, under the federal securities laws.

X. ADDITIONAL SCIENTER ALLEGATIONS

126. As alleged herein, Defendants acted with scienter in that Defendants knew, or recklessly disregarded, that the public documents and statements they issued or disseminated in the name of the Company (or in their own name) during the Class Period were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the federal securities laws. Defendants, by virtue of their receipt of information reflecting the true facts regarding Provectus, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements and/or their associations with the Company which made them privy to confidential proprietary information concerning Provectus, were active and culpable participants in the fraudulent scheme alleged herein.

127. Defendants knew and/or recklessly disregarded the falsity and misleading nature of the information which they caused to be disseminated to the investing public. The fraudulent scheme described herein could not have been perpetrated during the Class Period without the knowledge and complicity or, at least, the reckless disregard of the personnel at the highest levels of the Company, including the Individual Defendants.

128. The Individual Defendants, because of their positions with Provectus, controlled the contents of the Company's public statements during the Class Period. The Individual Defendants were provided with or had access to copies of the documents alleged herein to be false and/or misleading prior to or shortly after their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information, the Individual Defendants knew or recklessly disregarded that the adverse facts specified herein had not been disclosed to, and were being concealed from, the

public and that the positive representations that were being made were false and misleading. As a result, each of the Individual Defendants is responsible for the accuracy of the Company's corporate statements and is therefore responsible and liable for the misrepresentations contained therein.

XI. APPLICATION OF PRESUMPTION OF RELIANCE; FRAUD ON THE MARKET

129. Plaintiff will rely, in part, upon the presumption of reliance established by the "fraud on the market" doctrine in that, among other things:

(a) Defendants made public misrepresentations or failed to disclose material facts during the Class Period;

(b) the omissions and misrepresentations were material;

(c) the Company's common stock traded in an efficient market;

(d) the misrepresentations alleged would tend to induce a reasonable investor to misjudge the value of the Company's common stock; and

(e) Plaintiff and the other members of the Class purchased Provectus common stock between the time Defendants misrepresented or failed to disclose material facts and the time the true facts were disclosed, without knowledge of the misrepresented or omitted facts.

130. At all relevant times, the market for Provectus common stock was efficient for the following reasons, among others:

(a) as a regulated issuer of stock, the Company filed periodic public reports with the SEC;

(b) Defendants regularly communicated with public investors via established market communication mechanisms, including through regular disseminations of press releases

on the major news wire services, and through other wide-ranging public disclosures, such as communications with the financial press, securities analysts, and other similar reporting services; and

(c) the average daily trading volume for Provectus stock during the Class Period was 1.976 million shares, with over 172 million shares of stock outstanding in March 2014, and a market capitalization reaching approximately $1 billion during the Class Period.

131. As a result of the foregoing, the market for Provectus common stock promptly digested current information regarding Provectus from all publicly available sources and reflected such information in the prices of the stock. Under these circumstances, all purchasers of Provectus common stock during the Class Period suffered similar injury through their purchase of Provectus common stock at artificially inflated prices and a presumption of reliance applies.

132. A Class-wide presumption of reliance is also appropriate in this action under the Supreme Court's holding in *Affiliated Ute Citizens of Utah v. U.S.*, 406 U.S. 128 (1972), because the Class' claims are, in large part, grounded on Defendants' material omissions. Because this action involves Defendants' failure to disclose material adverse information regarding the Company's business operations and financial prospects – information that Defendants were obligated to disclose – positive proof of reliance is not a prerequisite to recovery. All that is necessary is that the facts withheld be material in the sense that a reasonable investor might have considered them important in making investment decisions. Given the importance of the Class Period material misstatements and omissions set forth above, that requirement is satisfied here.

XII. NO SAFE HARBOR

133. The statutory safe harbor provided for forward-looking statements under certain circumstances does not apply to any of the allegedly false statements pleaded in this Complaint. Many of the specific statements pleaded herein were not identified as "forward-looking statements" when made. To the extent there were any forward-looking statements, there were no meaningful cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Alternatively, Defendants are liable for those any forward-looking statements because they knew that the statement was false or misleading when made. None of the historic or present tense statements made by Defendants were assumptions underlying or relating to any plan, projection or statement of future economic performance.

XIII. CLASS ACTION ALLEGATIONS

134. Plaintiff bring this action as a class action pursuant to Rule 23 of the Federal Rules of Civil Procedure on behalf of all persons who purchased or otherwise acquired Provectus publicly traded securities during the Class Period (the "Class"). Excluded from the Class are Defendants and their families, the officers and directors of the Company, at all relevant times, members of their immediate families and their legal representatives, heirs, successors or assigns, and any entity in which defendants have or had a controlling interest.

135. The members of the Class are so numerous that joinder of all members is impracticable. The disposition of their claims in a class action will provide substantial benefits to the parties and the Court. Provectus had over 172 million shares of stock outstanding in March 2014, owned by thousands of persons.

136. There is a well-defined community of interest in the questions of law and fact involved in this case. Questions of law and fact common to the members of the Class that predominate over questions which may affect individual Class members include:

(a) whether the Securities Exchange Act was violated by Defendants;

(b) whether Defendants omitted and/or misrepresented material facts;

(c) whether Defendants' statements omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;

(d) whether Defendants knew or deliberately disregarded that their statements were false and misleading;

(e) whether the prices of Provectus securities were artificially inflated; and

(f) the extent of damage sustained by Class members and the appropriate measure of damages.

137. Plaintiff's claims are typical of those of the Class because plaintiff and the Class sustained damages from defendants' wrongful conduct.

138. Plaintiff will adequately protect the interests of the Class and has retained counsel who are experienced in class action securities litigation. Plaintiff has no interests which conflict with those of the Class.

139. A class action is superior to other available methods for the fair and efficient adjudication of this controversy. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation makes it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

140. Plaintiff makes the allegations herein based upon the investigation of Plaintiff's counsel, which included a review of regulatory filings made by Provectus with the SEC, as well as other regulatory filings and reports, securities analysts' reports and advisories about the Company, press releases and other public statements issued by the Company, and media reports about the Company. Plaintiff believes that substantial additional evidentiary support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

XIV. COUNTS

COUNT I

For Violation of §10(b) of the Securities Exchange Act and Rule 10b-5 Promulgated Thereunder Against all Defendants

141. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

142. During the Class Period, defendants disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

143. Defendants violated §10(b) of the Securities Exchange Act and Rule 10b-5 in that they:

(a) employed devices, schemes and artifices to defraud;

(b) made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or

(c) engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of Provectus publicly traded securities during the Class Period.

144. Plaintiff and the Class have suffered damages in that, in reliance on the integrity of the market, they paid artificially inflated prices for Provectus publicly traded securities. Plaintiff and the Class would not have purchased Provectus publicly traded securities at the prices they paid, or at all, if they had been aware that the market prices had been artificially and falsely inflated by defendants' misleading statements.

145. As a direct and proximate result of Defendants' wrongful conduct, Plaintiff and the other members of the Class suffered damages in connection with their purchases of Provectus stock during the Class Period each time the true facts were disclosed and Provectus's share price fell.

COUNT II

For Violation of §20(a) of the Securities Exchange Act Against the Individual Defendants

146. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

147. Provectus is a primary violator of §10(b) and Rule 10b-5, promulgated thereunder.

148. The Individual Defendants acted as controlling persons of Provectus within the meaning of §20(a) of the Securities Exchange Act. Each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company and, therefore, is presumed to have had the power to control or influence, and during the Class Period did exercise their power to control and influence, the conduct giving rise to the violations of the federal securities laws alleged herein. The Individual Defendants prepared, or were responsible for preparing, the Company's press releases and SEC filings and made statements to the market in

SEC filings, annual reports, press releases, news articles, and conference calls. The Individual Defendants controlled Provectus and each of its employees.

149. The Individual Defendants were able to and did control the content of the various SEC filings, press releases, and other public statements pertaining to the Company during the Class Period. The Individual Defendants were provided with copies of the documents alleged herein to contain material misrepresentations and omissions prior to or shortly after their issuance and had the ability and/or opportunity to prevent the issuance of such documents or cause them to be corrected. Accordingly, the Individual Defendants are responsible for the accuracy of the Company's public reports and releases.

150. By virtue of their positions with the Company, and ownership of Provectus stock, the Individual Defendants had the power and authority to cause Provectus to engage in the wrongful conduct complained of herein. By reason of such conduct, defendants are liable pursuant to §20(a) of the Securities Exchange Act. As a direct and proximate result of the Individual Defendants' wrongful conduct, Plaintiff and other Class members suffered damages in connection with their purchases of the Company's securities during the Class Period.

XV. PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

(a) Determining that this action is a proper class action under Rule 23 of the Federal Rules of Civil Procedure;

(b) Awarding compensatory damages in favor of Plaintiff and all other Class members against all Defendants, jointly and severally, for all damages sustained as a result of Defendants' wrongdoing, in an amount to be proven at trial, including interest thereon;

(c) Awarding Plaintiff and the Class their reasonable costs and expenses incurred in this action, including counsel fees and expert fees; and

(d) Such other and further relief as the Court may deem just and proper.

XVI. JURY TRIAL DEMANDED

Plaintiff hereby demands a trial by jury.

Respectfully submitted,

DATED: April 6, 2014

GLANCY BINKOW & GOLDBERG LLP

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PROOF OF SERVICE VIA ELECTRONIC POSTING PURSUANT TO EASTERN DISTRICT OF TENNESSEE LOCAL RULES AND ECF RULES

I, the undersigned, say:

I am a citizen of the United States and am over the age of 18 and not a party to the within action. My business address is 1925 Century Park East, Suite 2100, Los Angeles, California 90067.

On April 6, 2015, I served the following document:

CONSOLIDATED AMENDED CLASS ACTION COMPLAINT FOR VIOLATION OF THE FEDERAL SECURITIES LAWS

By posting the document to the ECF Website of the United States District Court for the Eastern District of Tennessee, for receipt electronically by the parties as listed on the attached Court's ECF Service List.

And on any non-ECF registered parties:

By U.S. Mail: By placing true and correct copies thereof in individual sealed envelope: with postage thereon fully prepaid, which I deposited with my employer for collection and mailing by the United States Postal Service. I am readily familiar with my employer's practice for the collection and processing of correspondence or mailing with the United States Postal Service. In the ordinary course of business, this correspondence would be deposited by my employer with the United States Postal Service that same day.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on April 6, 2015, at Los Angeles, California.

s/ Leanne E. Heine
Leanne E. Heine